STUDY OF RELATIONSHIP BETWEEN CAROTID INTIMA-MEDIA THICKNESS AND SYNTAX SCORE IN PATIENTS WITH CORONARY ARTERY DISEASE

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CERTIFICATE

This is to certify that the dissertation titled "**STUDY OF RELATIONSHIP BETWEEN CAROTID INTIMA-MEDIA THICKNESS AND SYNTAX SCORE IN PATIENTS WITH CORONARY ARTERY DISEASE"** is the bonafide original work of Dr**. S. RETNARAJ**, in partial fulfillment of the requirements for D.M. Branch-II (CARDIOLOGY) examination of THE TAMILNADU DR.M.G.R. MEDICAL UNIVERSITY to be held in August 2014. The period of post-graduate study and training was from August 2011 to July 2014.

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DECLARATION

I, **Dr.S. RETNARAJ**, solemnly declare that this dissertation entitled, "**STUDY OF RELATIONSHIP BETWEEN CAROTID INTIMA-MEDIA THICKNESS AND SYNTAX SCORE IN PATIENTS WITH CORONARY ARTERY DISEASE**" is a bonafide work done by me at the department of Cardiology, Madras Medical College and Government General Hospital during the period 2011 – 2014 under the guidance and supervision of the Professor and Head of the department of Cardiology of Madras Medical College and Government General Hospital, Professor M.S.Ravi M.D.D.M. This dissertation is submitted to The Tamil Nadu Dr. M.G.R Medical University, towards partial fulfillment of requirement for the award of **D.M. Degree (Branch-II) in Cardiology**.

Place: **SIGNATURE OF THE CANDIDATE**

Date:

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CONTENTS

INTRODUCTION

Globally before 1900, Death due to cardiovascular diseases accounted only less than 10% of all deaths. This period is called as age of pestilence and famine. Instead malnutrition and infections were responsible for most common causes of death. Predominant types of cardiovascular diseases in that period were RHD, cardiomyopathies caused by infection and malnutrition.

Age of the receding Pandemics[1]

During the early 20th Century improvements in agricultural production, food supply and industrial revolution led to reduced mortality due to malnutrition. Moreover improved public health measures reduced infections life expectancy improved. Typical proposition of death due to cardiovascular causes were between 10-35%. Cardiovascular diseases predominant were RHD, Hypertension, CHD, and Stroke.

Degenerative and man-made diseases

During this next phase which occurred in different periods in different parts of the world there is continuous in improvements in economic situation there is rapid urbanisation and radical changes in the nature of the work related activities. Both of these combined together leading to dramatic changes in the life style of the people in diet, activity levels and behaviors such smoking. The increased caloric intake combined with reduced caloric expenditure caused by mechanization resulted in high body mass index with in turn led to increased blood pressure → increased level of lipids → increased sugars. This sets the

stage for hypertension and atherosclerotic diseases. Mortality due to cardiovascular causes was 35-65%, mostly due to Coronary artery disease and stroke.

Delayed degenerative Phase[2]

In the industrialized nations major technological advances such as coronary care units/ Thrombolytic therapy / Bypass surgery/Percutaneous coronary interventions are available to manage acute manifestations of Cardiovascular diseases and preventive strategies like smoking cessation programs blood pressure management and cholesterol management are widely implemented age adjusted CV diseases mortality declined. CVD is affecting older and older individuals. Proportion of deaths caused by cardiovascular diseases is about 40-50% mainly due to CHD, Stroke and Congestive heart failure.

The fifth phase is the Age of inactivity and obesity even through there is measurable improvements in risk behaviors, especially smoking. Physical activity continues to decline while caloric intake is increasing dramatically resulting in overweight and obesity. Type II DM and Hypertension are on raise especially in children.

In India in 1960 CHD represented only 4% of CVD deaths where as in 1990.[3] The proportion was greater than 50%. Indians have exaggerated insulin insensitivity towards western life style which differently increased CHD and Stroke. Thus environmental factors have now become globalised. We are well aware that atherosclerosis is the major causes of CVD discussed above. Our understanding about atherosclerosis has improved. Atherosclerosis can affect large and medium arteries. Postmortem and IVUS Studies have revealed wide

spread intimal thickening in patients with atherosclerosis. At the same time atherosclerosis is a focal disease affecting certain areas of the vessels more; for example the branching point of arterial tree. Atherosclerosis is chronic disease with prolonged incubation period. It begins in the childhood and progresses gradually over decades. Increasing population awareness about factors causing atherosclerotic progression and CVD and measures to prevent development of these risk factors and their progression to manifest disease is an important step in reducing the burden of CVD. Even though this is an important step at the mass level due to general apathy of the public towards such measures it fails to produce desired effects. It will be more effort effective and desirable if we adopt an alternative approach of identifying individuals having high risk

Identification of high risk individuals has been traditionally achieved using one of the many global risk assessment algorithms available such as

Framingham risk score – FRS[7]

Heart Systematic coronary risk evaluation project or Heart score.

Prospective cardiovascular Munster (PROCAM) study.

New Zealand guidelines

WHO risk score etc.

Although the value of these algorithms has been established in a number of clinical trials there is still a significant variation at every level

of risk factor exposure which limits our ability to predict risk at individual level.

Many of the algorithms predict only 10 year risk (New Zealand guidelines predicts 5 years risk) which is relatively meaningless in young individuals, obese persons, Patients with metabolic syndrome etc.

Patients with extremely high levels of dyslipidemia, such as genetic dyslipidemia may not be adequately classified.

In Heart score – Diabetes was not included because it was not reliably measured in cohorts used to develop scores.

In view of the above imperfect relationship between CV risk factors and actual development of disease there has been increasing emphasis of developing tools that can directly detect vascular disease itself at a subclinical stage rather than relying on indirect risk prediction through these risk factors. The prolonged preclinical phase of atherosclerosis helps us to detect it at a stage where it can be potentially reversed with interventions, even if it cannot be reverted its progression can be at least be halted and its transformation in to clinical CV event such as i). Progression to flow limiting lesion causing ischemia. ii). Plaque fissure, rupture/erosion – thrombus formation can be prevented.

A number of non invasive tools have been detected over the past 3 decades to identify the preclinical atherosclerosis. These include carotid – intima media thickness,[8,9] brachial artery flow mediated dilation, coronary artery calcium score, pulse wave velocity of aorta etc. of these CIMT is easily done, reproducible most extensively evaluated in clinical trials and

therefore currently recommended for use in clinical practice. The study of relationship between carotid intima-media thickness and syntax score in patients with coronary artery disease is nothing but a correlative study to show that those with extensive coronary artery disease as assessed by SYNTAX score have high prevalence of carotid intima – media thickness and plaque score. In one pilot study, carotid intima – media thickness <0.55 mm was an excellent predictor of absence of coronary artery disease and obviated the need for invasive coronary angiography before heart valve surgery.[10]

REVIEW OF LITERATURE

SYNTAX SCORE

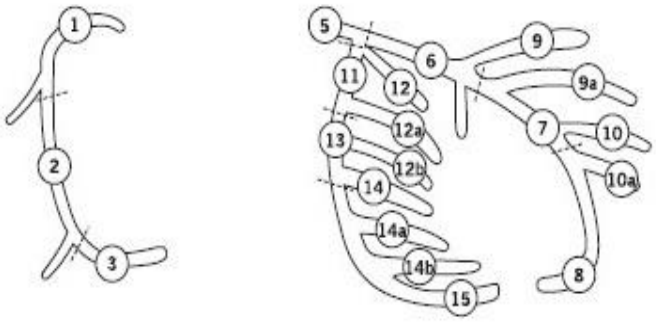
Optimal revascularisation for patients with coronary artery disease was a strong debate between surgeons and interventional cardiologist. To answer this question syntax score was developed from integration of many available previous scoring systems. This scoring helped us to find out the complexity of coronary artery lesions so that those with high and intermediate syntax score was subjected to CABG and those with low syntax score can undergo PTCA with stenting which is less invasive then surgery. Thus syntax score is an angiographic tool which reflects the complexity of coronary artery disease.

SYNTAX (Synergy between PCI with TAX us and cardiac surgery) Study was an all corner study for patients with significant lesions in the left main / and or three epicardial coronary arteries.

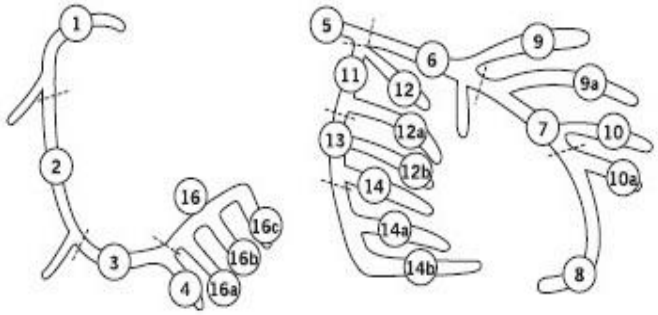
Syntax score was developed based on the integration of the following.

AHA classification[11] of coronary segments modified for ARTS[12] study. By AHA classification which is later modified for ARTS study coronary tree segments were divided in to 16 segments and as such has been integrated in to syntax score.

Left dominance



Right dominance



Definition of the coronary tree segments

1. *RCA proximal: From the ostium to one half the distance to the acute margin of the heart.*

2. *RCA mid: From the end of first segment to acute margin of heart.*

3. *RCA distal: From the acute margin of the heart to the origin of the posterior descending artery.*

4. *Posterior descending artery: Running in the posterior interventricular groove.*

16. *Posterolateral branch from RCA: Posterolateral branch originating from the distal coronary artery distal to the crux.*

16a. *Posterolateral branch from RCA: First posterolateral branch from segment 16.*

16b. *Posterolateral branch from RCA: Second posterolateral branch from segment 16.*

16c. *Posterolateral branch from RCA: Third posterolateral branch from segment 16.*

5. *Left main: From the ostium of the LCA through bifurcation into left anterior descending and left circumflex branches.*

6. *LAD proximal: Proximal to and including first major septal branch.*

7. *LAD mid: LAD immediately distal to origin of first septal branch and extending to the point where LAD forms an angle (RAO view). If this angle is not identifiable this segment ends at one half the distance from the first septal to the apex of the heart.*

8. *LAD apical: Terminal portion of LAD, beginning at the end of previous segment and extending to or beyond the apex.*

9. *First diagonal: The first diagonal originating from segment 6 or 7.*

9a. *First diagonal a: Additional first diagonal originating from segment 6 or 7, before segment 8.*

10. *Second diagonal: Originating from segment 8 or the transition between segment 7 and 8.*

10a. *Second diagonal a: Additional second diagonal originating from segment 8.*

11. *Proximal circumflex artery: Main stem of circumflex from its origin of left main and including origin of first obtuse marginal branch.*

12. *Intermediate/anterolateral artery: Branch from trifurcating left main other than proximal LAD or LCX. It belongs to the circumflex territory.*

12a. *Obtuse marginal a: First side branch of circumflex running in general to the area of obtuse margin of the heart.*

12b. *Obtuse marginal b: Second additional branch of circumflex running in the same direction as 12.*

13. *Distal circumflex artery: The stem of the circumflex distal to the origin of the most distal obtuse marginal branch, and running along the posterior left atrioventricular groove. Caliber may be small or artery absent.*

14. *Left posterolateral: Running to the posterolateral surface of the left ventricle. May be absent or a division of obtuse marginal branch.*

14a. *Left posterolateral a: Distal from 14 and running in the same direction.*

14b. *Left posterolateral b: Distal from 14 and 14 a and running in the same direction.*

15. *Posterior descending: Most distal part of dominant left circumflex when present. It gives origin to septal branches. When this artery is present, segment 4 is usually absent.*

Leaman Score[13]

It is based on the severity of luminal diameter and weighing factor given to each segment of coronary tree that supplies the left ventricle. For lesion with 50-99% reduction in luminal diameter a multiplication factor of 2 is used. For lesions with 100% occlusion, multiplication factor is 5 reflecting difficulty in treating percutaneously. In the right Dominance system, RCA supplies 16% of the LV. LCA supplies 84% of which LAD supplies 66% and LCX supplies 33%.

Thus LM supplies approximately 5 times, LAD approximately supplies 3.5 times (84/16 X 0.66), LCX supplies 1.5 times of that of RCA

In the left dominant system for weighing factor left main is 6

For LAD it is 3.5 [58%]

For LCX it is 2.5 [42%]

Contribution by each segment of coronary artery to the blood flow of the LV is used as a multiplication factor for the calculation of syntax score.

Segment weighing factors

Segment No		Right dominance	Left dominance
1	RCA proximal	1	0
2	RCA mid	1	0
3	RCA distal	1	0
4	Posterior descending artery	1	n.a.
16	Posterolateral branch from RCA	0.5	n.a.
16a	Posterolateral branch from RCA	0.5	n.a.
16b	Posterolateral branch from RCA	0.5	n.a.
16c	Posterolateral branch from RCA	0.5	n.a.
5	Left Main	5	6
6	LAD proximal	3.5	3.5
7	LAD mid	2.5	2.5
8	LAD apical	1	1
9	First diagonal	1	1
9a	First diagonal[a]	1	1
10	Second diagonal	0.5	0.5
10a	Second diagonal[a]	0.5	0.5
11	Proximal circumflex artery	1.5	2.5
12	Intermediate/ anterolateral artery	1	1
12a	Obtuse marginal[a]	1	1
12b	Obtuse marginal[b]	1	1
13	Distal circumflex artery	0.5	1.5
14	Left posterolateral	0.5	1
14a	Left posterolateral[a]	0.5	1
14b	Left posterolateral[b]	0.5	1
15	Posterior descending	n.a.	1

If multiple lesions are less than 3 vessel reference diameters away they are considered as a single lesion.

ACC/AHA classification[14]

Depending upon the parameters like lesion length, eccentricity, angulation, calcification, involvement of side branches, thrombus and severity of stenosis.

Type A (High success and low risk)

Type B (moderate success and moderate risk)

Type C (Low success and High risk)

Majority in the above classification is incorporated in syntax score. Total occlusions, trifurcations and bifurcations are not dealt separately in ACC/AHA classification.

Total occlusion classification system parameters like

Age of the lesion more than 3 months or unknown, blunt stump

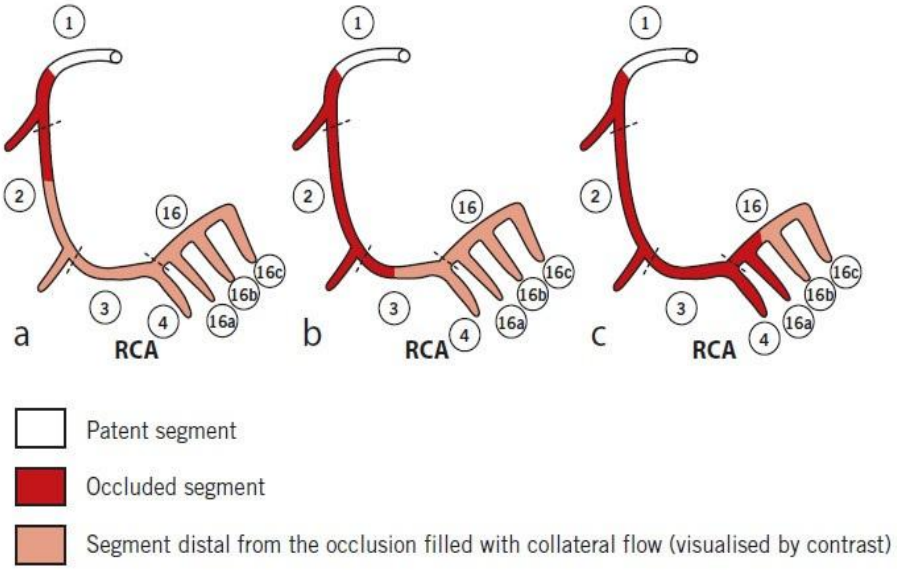
Filling by bridging collaterals

Side branch yes if <1.5 mm

Yes Both <& >1.5 mm

are given weightage and each of the above given +1 mark,

The length of the obstructed segment is calculated by measuring the distance between the stump and the first segment beyond the occlusion filled by antegrade or retrograde, ipsilateral or contralateral collaterals +1/ per non-visible segment is given



Total occlusion length assessment
a) Total occlusion involving segments 1 and 2. Segments 2,3,4,16,16a,16b,16c are filled by antegrade or retrograde collateral flow (visualised by contrast).
b) Total occlusion involving segments 1, 2 and 3. Segments 3,4,16,16a,16b,16c are filled by antegrade or retrograde collateral flow (visualised by contrast).
c) Total occlusion involving segments 1, 2, 3, 4, 16 and 16a Segments 16,16b,16c are visualized by antegrade or retrograde collateral flow (visualised by contrast).

Trifurcation lesion

One main vessel and two side branches with a minimal diameter of 1.5 mm

For 1 diseased segment score is +3

For 2 diseased segment score is +4

For 3 diseased segment score is +5

For 4 diseased segment score is +6

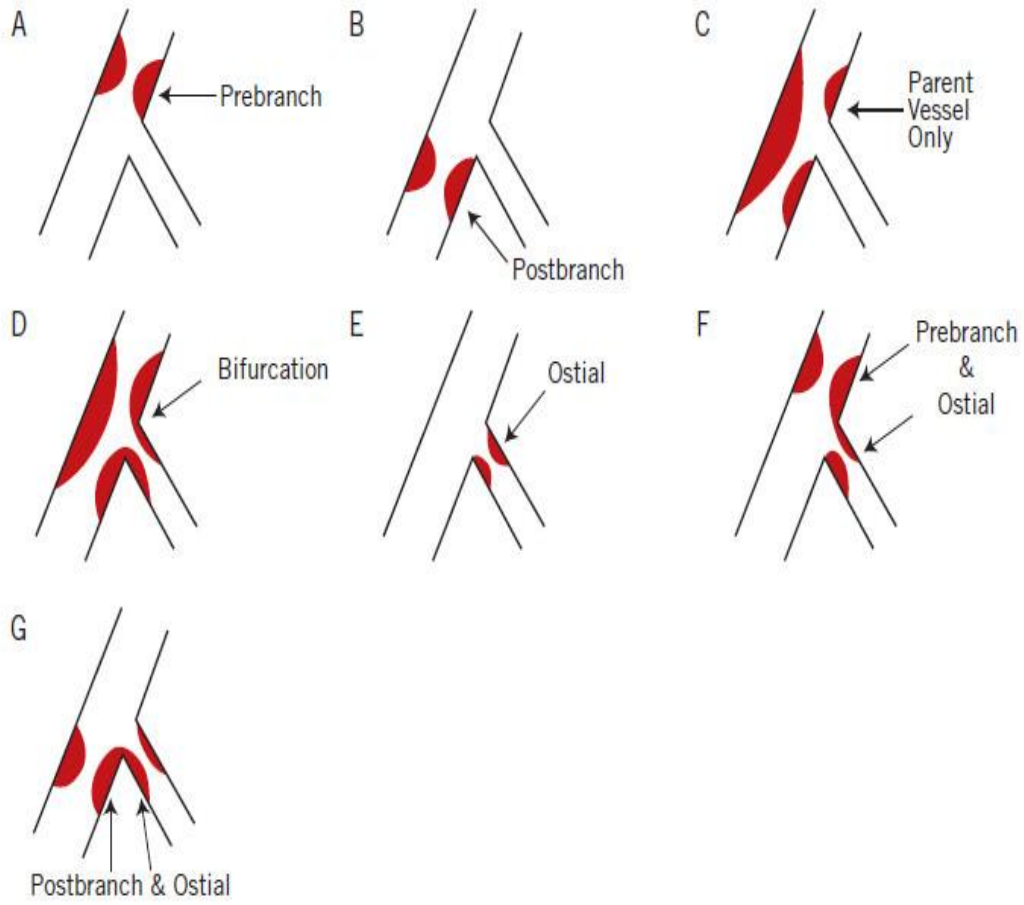
Segments for trifurcation

3,4,16,16a 5,6,11,12, 11/12 a/12b/13

6,7,9,9a 7,8,10,10a

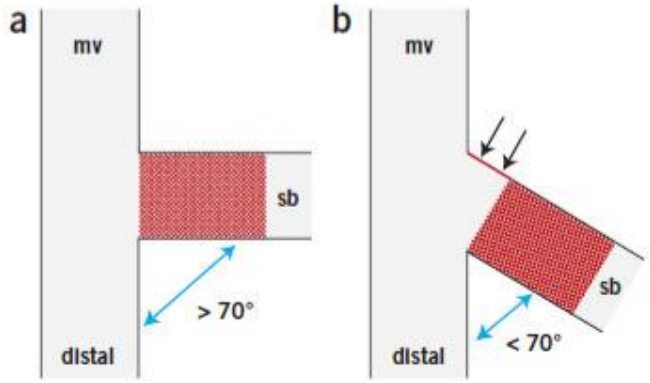
Duke's and ICPS bifurcation lesion classification system

Junction of main vessel with a side branch >1.5mm



For A, B, C score is +1

D, E, F, G Score is +2



Angulation < 70 → score is +1

[Because it is more difficult to cover the ostium of side branch when stenting is necessary]. Following segments are considered for bifurcation lesions.

5,6,11 6, 7, 9, 7,8,10

11/13/12a 13/14/14a 3/4/16

13/14/15 in LD

Aorta – ostial Lesion

Applies to segments 1 and 5, in case of separate ostium of CAD and LCX it is 6 and 11. It is an adverse lesion since treatment of such lesion is more challenging.

Diffuse Disease / small vessels.

When >75% of the segment distal to the lesion has diameter less than 2mm irrespective of the presence or absence of lesion.

Thus in SYNTAX score algorithm has 12 sequential and interactive self guided questions they can be divided in the two groups

Group I

1. Dominance
2. Total number of lesions (maximum allowed is 12)
3. Vessels segments involved per lesion

Group II

4. Total Occlusion.

Age of occlusion >3 months --- +1

Blunt stump --- +1

Bridging collateral --- +1

First segment beyond occlusion -- +1 per non-visible segments

Side branch involvement yes Side Branch <1.5mm –--- +1

Yes both Side Branch < &> 1.5mm----+1

5. Trifurcation

Number of segments involved (1 diseased segment +3)

6. Bifurcation

i). Type A, B, C +1

ii). Type D, E, F, G +2

iii). Angulation <70° +1

7. Aorto – ostial location +1
8. Severe tortuosity +2
9. Length >20mm +1
10. Heavy calcification +2
11. Thrombus +1
12. Diffuse / Small vessel Disease +1 per segment number

Tortousity means 1 bend >90°, 3 or more bends of 45°-90° proximal to diseased segment

Heavy calcification if seen in more than one projection surrounding the complete lumen of coronary artery at the site of the lesion.

Thrombus: Spherical, ovoid, irregular filling defect surrounded on three sides by the contrast .Based on the above algorithm each lesion is given a particular score and the scores of individual lesions are summed to arrive at the final score.

Syntax score focused also on coronary artery anatomy rather than treatment plan alone.

In addition to optimal treatment plan, it compares the coronary artery disease complexity in individual patients and in entire patient cohort as well

An assessment of adequacy and completeness of revascularization

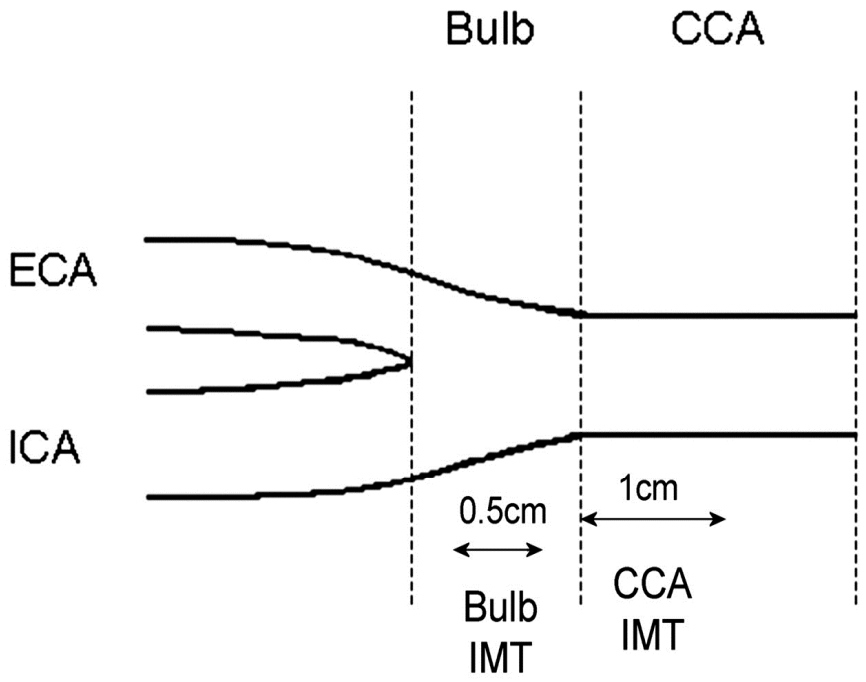
II. Carotid intima media thickness represents the combined thickness of intima and media layers of carotid artery which can be assessed by B- mode ultrasonogram and media thickness may not necessarily be a consequence of atherosclerosis directly but still related to it because the cellular / molecular mechanisms that increases CIMT are also the factors responsible for the development and progression of atherosclerosis. Moreover significant technical advancements were made in the past two decades to easily measure CIMT. As a result CIMT represents sub – clinical vascular disease, that has been unequivocally proven by numerous clinical and autopsy studies.

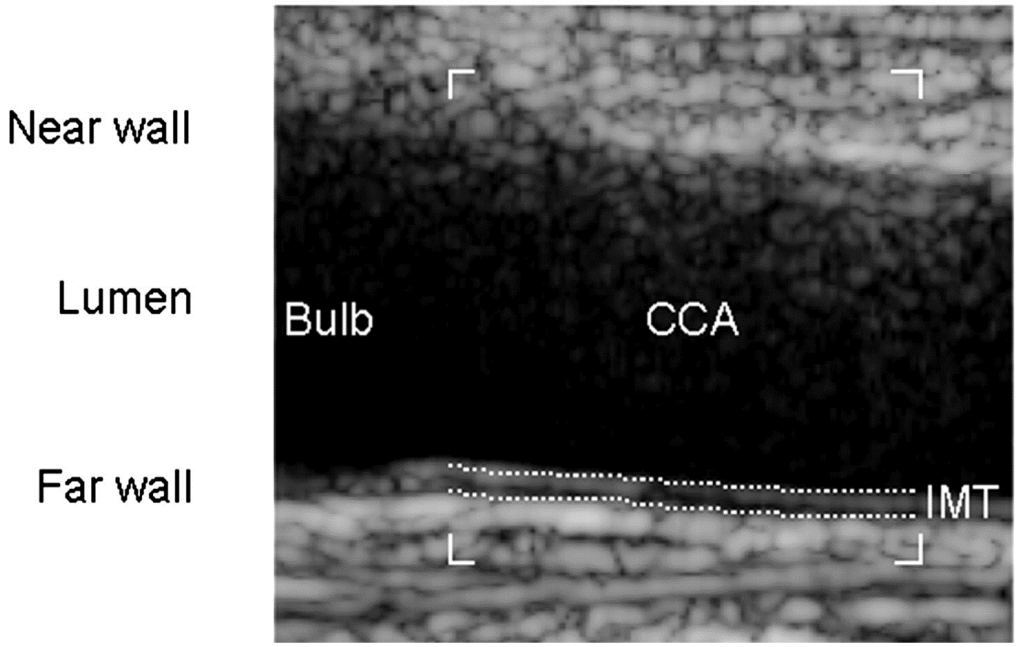
American society of echocardiography[15] has standardized technique for assessment of CIMT. Use of automated border detection software is additionally recommended to ensure optimal accuracy and reproducibility.

Small errors in CIMT measurement can classify patients into different risk categories. Adherence to prescribed imaging protocol and close attention to instrumentation are critical for image acquisition and analysis.

The patient is made to lie in supine position with slight hyper extension of neck and rotated in opposite direction. The vascular probe used to image carotid artery contains a linear phased array transducer with minimum fundamental frequency of 7MHz. ECG is connected for obtaining R wave gated images.

First the whole of the extra cranial carotid arterial system is scanned to identify those vessels and to look for the presence of plaques, followed by intima – media thickness measurement although atherosclerosis and CIMT progresses more rapidly in bulb and internal carotid segments


Bulb
CCA
ECA
ICA
0.5cm
1cm
Bulb
IMT
CCA
IMT


Near wall
Lumen
Far wall
Bulb
CCA
IMT

CIMT measurement is now restricted only to Common Carotid Arteries.

Common carotid artery is imaged in longitudinal plane and optimal angle of incidence is identified. Optimal angle of incidence is the plane in which the bifurcation of the carotid bulb in to internal and external carotid arteries at the tip of the flow divider can be seen simultaneously with bulb and distal CCA which is called as tuning fork view. Finer adjustments are then made to ensure distal CCA as horizontal are seen in both near and far walls of CCA [also called as double line sign]

CCA is additionally imaged in two orthogonal views 45◦ anterior and 45 posterior to the first image and cine loops of images are stored.

Using automated software which lines lumen of intima, media – adventitia interfaces over short distance are used to measure CIMT. Six values of CIMT are averaged to get mean CIMT. Carotid plaques are focal wall thickening that is at least 50% greater than the surrounding vessel or focal region with CIMT >1.5mm that protrudes in to the lumen.

CIMT values ≤25th percentile is considered as lower CVD risk. Values in 25^{th} -75^{th} percentile are considered as average risk and indicative of unchanged CVD risk. CIMT values ≥ 75^{th} percentile for the same age, gender and ethnic group are considered as increased CVD risk while comparing CIMT values with reference to study population it is important to follow the same measurement protocol as significant heterogeneity exists among different studies due to different protocols used to measure IMT vs. Plaque.

Carotid wall thickening is not always synonymous with atherosclerosis where as plaque is a direct consequence of atherosclerosis. However CIMT offers certain advantages over plaques. It may be a better marker of total body atherosclerosis whereas a localized plaque is primarily a marker of carotid atherosclerosis.

Moreover quantification of plaque is technically challenging and no standard protocol exists. As a result it is easier to asses graded increase in CV risk with CIMT.

CIMT as a marker of Atherosclerosis

In ARIC[16] (Atherosclerosis risk in communities) study relationship of CIMT to coronary heart disease.

CHD incidence was studied in 7289 women and 5552 men aged 45-64 years who were free of CAD at baseline after 4-7 years of follow up, a graded relationship was found between CIMT and risk of CHD events. Those with mean CIMT > 1mm had hazard ratios of 5.07 and 1.85 for CHD events for women and men respectively.

A report from ARIC study describing the data on 3, 870 black white men and women aged 45-64 years showed, substantially greater CIMT values in patients with clinically manifest CVD.

In cardiovascular Health study[17] which included 5858 elderly subjects, CIMT again showed a linear association with the risk of MI or stroke. The association was independent of traditional CV risk factors.

A subgroup analysis of Rotterdam study[18] population has also shown significant association between increased CIMT and future CV events independent of age, sex and history of MI or stroke.

In METEOR study[19] rosuvastatin reduced progression of CIMT in 984 middle aged adults at apparently low to intermediate CVD risk but with increased CIMT. This study indirectly implied statin therapy is beneficial for those individuals who otherwise would not have qualified for it based on current treatment guidelines.

In women's Healthy life style project,[20] and accelerated CIMT progression was noticed during menopause and diet / exercise intervention slowed this process

In Los Angeles atherosclerosis study[21] increased physical activity and increased dietary fiber intake reduced progression risk of CIMT.

In MARS (Monitored atherosclerosis regression study) Project it was estimated that combination of smoking cessation, weight loss aided dietary choices consumption could significantly reduce rate of progression.

Correlation between intima-media thickness versus syntax score.

Carotid artery intima-media thickness and plaque score can also predict the syntax score as shown in a recent study by Nobutaka Ikeda et al.[25] The principal finding of this study was carotid – US findings correlated with complexity of CAD thus CIMT seems reasonable for risk stratification of asymptomatic but otherwise clinically at risk individuals for potential CV events. The importance of pretest risk in identifying the relevant population for these tests should be emphasized.

In a study by Adnan Delic et al[23] carotid ultrasonogram has sufficient. Sensitivity and specificity in detection of patients with high risk of significant CAD and it is an argument for broader use of carotid ultrasound for evaluation of patients who are considered for coronary angiography.

In a study by levent Korkmaz et al[24] mean CIMT and overall SYNTAX score were 0.87± 0.12 mm and 15±9 respectively. Univariate analysis showed significant correlation between overall SYNTAX SCORE and CIMT.

In a study by P. Viswakarma et al[26] the odds ratio associated with mean IMT and plaque score for prediction of intermediate and high SYNTAX score were 1.18 and 1.30 respectively. In addition the plaque score and mean IMT showed excellent negative predictive value in the presence of complex coronary artery lesion.

AIMS AND OBJECTIVES

To study the complexity of coronary artery disease in stable CAD patients undergoing coronary angiogram by assessing SYNTAX score.

To study the carotid intima- media thickness of patients who underwent coronary angiogram.

To study the relationship between carotid intima – media thickness and SYNTAX score in patients with coronary artery disease.

MATERIALS AND METHODS

The study was conducted in the department of cardiology at Rajiv Gandhi government general hospital. Patients with stable chronic coronary artery disease who underwent coronary angiogram were selected for this study. Patients with chronic stable angina were enrolled for angiogram either directly or following positive stress test

STUDY GROUP SELECTION

Institutional ethics committee approval was obtained to conduct this study in our hospital. All the patients were provided with a written informed consent form in the language known to them before participating in the study.

Exclusion criteria

Patients not willing for coronary angiography

Patients who were allergic to contrast agents

Those who are having underlying chronic kidney disease

Patients with heart failure

Those with acute myocardial infarction

CLINICAL EVALUATION

Before coronary angiogram patients were evaluated with complete blood count, Blood urea, serum creatinine, coagulation profile serum electrolytes, Electrocardiogram and chest x-ray were done. A detailed

record of the patient's history was taken Those patients with chronic stable angina were enquired about the character of pain, frequency, radiation, duration, NYHA class etc, other symptoms which were analyzed include

Dyspnoea:

Dyspnoea duration, NYHA class, paroxysmal nocturnal dyspnoea, orthopnoea

Palpitation

Exertional or rest, onset, offset

Anginal equivalents

Syncope, fatigue and pedal edema

History risk factors like smoking, duration of smoking, number of cigarettes smoked per day

History of dyslipidemia, treatment for dyslipidemia, family history of dyslipidemia.

History of hypertension,

Duration drugs for hypertension,

Complications

Family history of Coronary artery disease

Past history of coronary artery disease

History of alcohol consumption

Duration of alcoholism, amount of alcohol consumed

The history of diabetes was enquired, the duration, treatment and complications if any were recorded.

Female patients had a menstrual history obtained and classified as pre or post menopausal.

All anthropometric measurements including height, weight and BMI were obtained in all study participants. Waist hip ratio, pulse, JVP and Blood pressure were recorded.

Detailed examination of cardiovascular and other systems was done.

ECG was done in every patient and the findings were recorded.

Echocardiogram was done using Philips HD7XE machine. Patients were assessed for LV systolic function –Ejection Fraction, Chamber dimensions, valve pathology, pulmonary artery pressures, RV function, presence of clot, origin of proximal coronary arteries and regional wall motion abnormalities.

Coronary angiogram was done in our cathlab; the angiographic setup used was Toshiba Infinix angiographic suite. All patients were taken for coronary angiogram after taking informed consent from the patient. Pre procedure skin preparation, injection Tetanus Toxoid and Lignocaine test dose was given to all patients. Diabetic patient who were

on oral hypoglycemic agents where changed over to regular insulin as per the diabetologist advice.

Coronary angiogram was done by radial or femoral route. Majority of patient underwent coronary angiogram through the femoral route.

Standard coronary angiographic views were obtained for all patients and special views were done when necessary.

In majority of patients coronary angiogram was done via the femoral route and standard 6F Judkins 3.5 or 4 Judkins left and right catheter was used to engage the left coronary and right coronary artery respectively. If the coronary angiogram was done through the radial route 5F tiger catheter was used. Optimal angiographic views were taken to assess the lesion characteristics .Coronary arteries are visualized after iohexol contrast injection

Coronary artery disease was diagnosed by coronary angiography if the diameter stenosis of the involved vessel is more than 50 percentage compared to the normal reference vessel luminal diameter.

If the patients were found to have coronary artery disease the SYNTAX score was calculated.

SYNTAX score was electronically calculated by syntax calculator online through twelve step sequential interactive question method. All the coronary angiograms were analyzed for syntax score calculation and the results were graded as low, intermediate and high scores. The coronary vessels with a luminal diameter of more than 1.5mm were studied separately and they were classified to have stenosis if more than 50% diameter was affected and scoring was done .a multiplication factor of 2

was used for lesions ranging from 50 to 99% and a multiplication factor of 5 was given to total occlusions. Other morphologies that resulted in an additive scoring pattern were ostial lesions, branch lesions such as bifurcation and trifurcation lesions, side branch lesions, angulations, vessel tortuosity, calcific lesions very long lesions and diffuse lesions. Presence of thrombus also had an additive value.

Estimation Carotid intima media thickness and plaque score:

Patients were referred to the department of Radiology and imaging for the detailed assessment of carotid intima and media thickness and also for scoring of carotid plaques.

Experienced radiologists with expertise in carotid ultrasonography performed the imaging using high resolution B-mode, pulse wave Doppler and colour Doppler ultrasound using a GE 4D ultrasound Doppler machine with a 7.5 MHz linear array probe.

Technique

American Society of Echocardiography guidelines for CIMT measurement was followed uniformly in all patients

Supine position with Head tilted backwards

Probe rotated 90 degrees after locating the carotid arteries

Recording of both anterior and posterior walls of the carotid in a longitudinal plane

Both common carotid and internal carotids were studied

CIMT definition

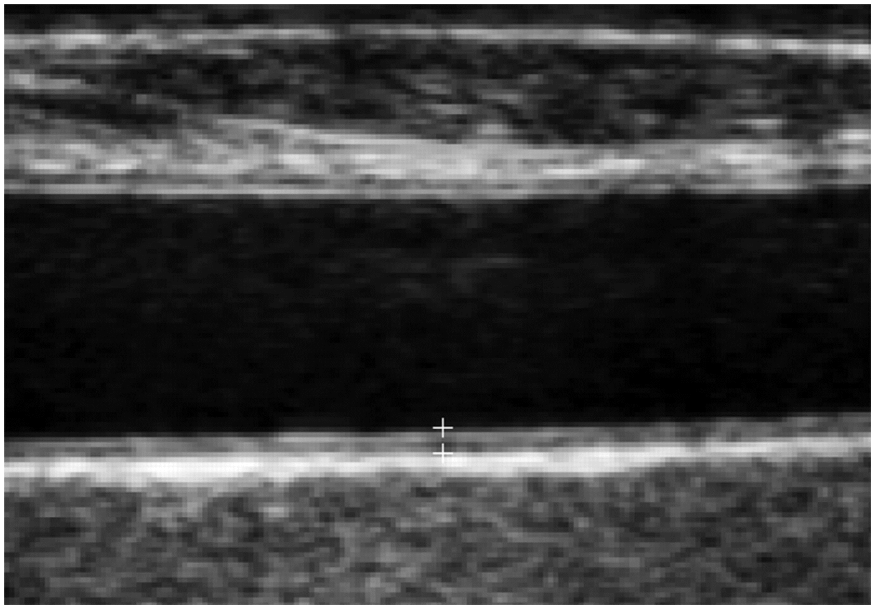
The distance between the leading edge of lumen intima interface and the leading edge of the media adventitia interface was taken as the carotid intima media thickness.

An average of three measurements were taken and a mean CIMT value was calculated.

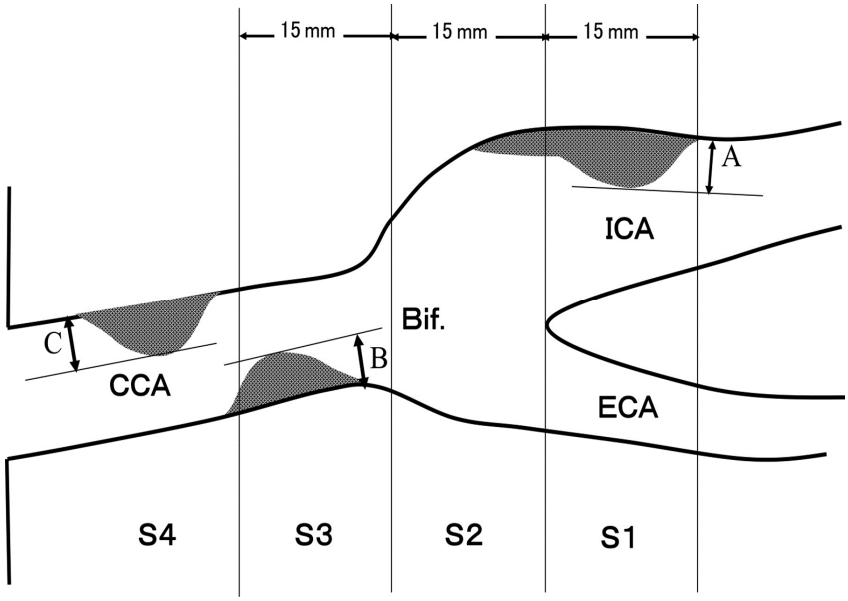
Plaque identification:

A focal thickening of the intima and media of more than or equal to 1.1 mm was taken as a plaque. Plaques found in both carotid arteries were assessed and sum of the plaque thickness was taken as the plaque score. Only thickness alone was taken into account and the length was not given any significance.

Carotid intima media thickness



Analysis of the plaque score



Statistical Analysis

The collected data was entered in Microsoft excel spread sheet and analysed using Statistical Package for Social Sciences software (SPSS version 17.0). Categorical data are presented as absolute values and percentages, whereas continuous data are summarized as mean value ± standard deviation. Independent sample‘t’ test and Chi - square tests were used for comparison of categorical variables as appropriate. Significance was considered if the ‘p’ value was below 0.05.

RESULTS AND ANALYSIS OF DATA

Forty patients with stable coronary artery disease underwent coronary angiogram were taken into study population and they underwent carotid Doppler ultrasound examination to measure the intima-media layer thickness of carotid arteries and plaque score.

In our study of total number of patients were 40. Out of 40 patients 8 patients were females constituting 20 % of the study population. The gender distribution of the study population is depicted in table no. 1

Table 1: Gender distribution of study population

S. No.	Sex	Number of Patients	Percentage
1	Male	32	80 %
2	Female	8	20 %
Total		40	100 %

Figure 1: Gender distribution

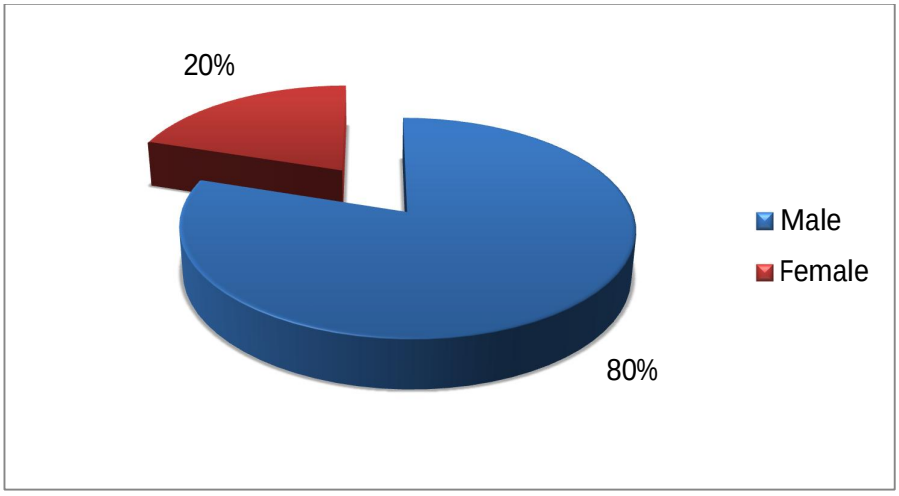
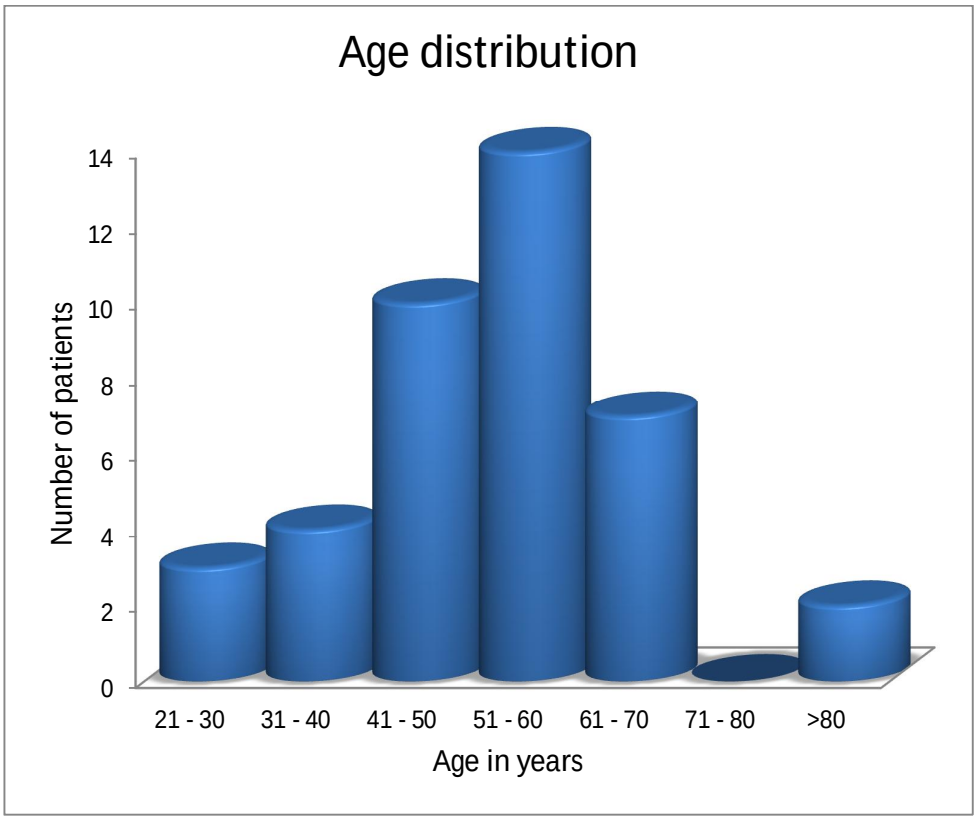


Table 2: Age wise distribution of patients

S. No.	Age Group	Number of Patients	Percentage
1	21 – 30	3	7.5 %
2	31 – 40	4	10 %
3	41 – 50	10	25 %
4	51 – 60	14	35 %
5	61 – 70	7	17.5 %
6	71 – 80	0	0 %
7	>80	2	5 %

In our study, 3 patients are below the age of 30 years. The most common age group in our study is 51 – 60 years in which 14 patients are there. 2 patients are having age more than 80 years. The age wise distribution of the patients are depicted in Table No. 2

Figure 2: Showing Age wise distribution of patients



TRADITIONAL RISK FACTORS:

The traditional cardiovascular risk factors have been analysed in the patient population.

Smoking :

Among 40 patients, 28 were smokers constituting 70 % of the study population. Among non smokers 8 were females. Smoking was not present in female patients.

Hypertension :

Half of the population was having systemic hypertension.

Diabetes Mellitus :

Type 2 diabetes mellitus was present in 8 patients who constitute 20 % of the study population. When compared to hypertensives, diabetics were less in prevalence.

Dyslipidemia :

Dyslipidemia which is an important risk factor for the development of coronary artery disease was found in 4 patients and forming about 10 % of the study population.

Postmenopausal :

Among 8 females, 4 females were postmenopausal 0 comprising of 50 % of the female population studied.

Family History of CAD :

Positive family H/o was present in 8 persons constituting 20 % of the study population.

Alcoholism :

Alcoholism was prevalent among male population. Of the total 32 males, 26 patients have been consuming alcohol. They form about 81.2 % of the male study population. The risk factors prevalent among study population are shown in Table No. 3 and in Figures 3 to 6.

Table 3: Risk Factors

S. No.	Risk Factors	Number of Patients	Percentage
1	Smokers	28	70 %
2	Hypertension	20	50 %
3	Diabetes	8	20 %
3	Dyslipidemia	4	10 %
4	Post Menopausal	4	10 %
5	Family H/o of CAD	8	20 %
6	Alcoholism	26	65 %

Figure 3: Showing Prevalence of Smoking

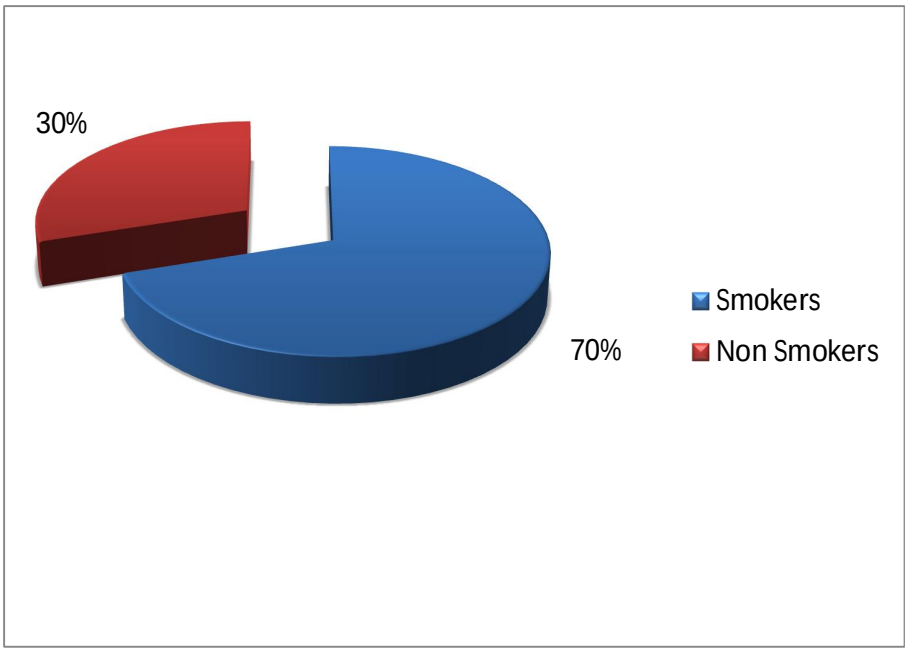


Figure 4: Showing Prevalence of Hypertension

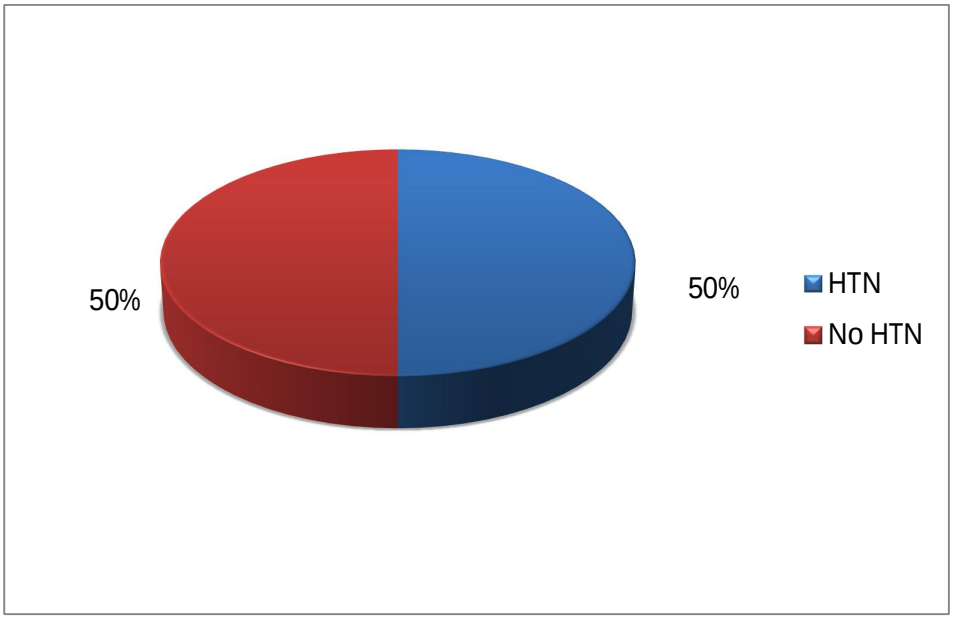


Figure 5: Showing Prevalence of Dyslipidemia

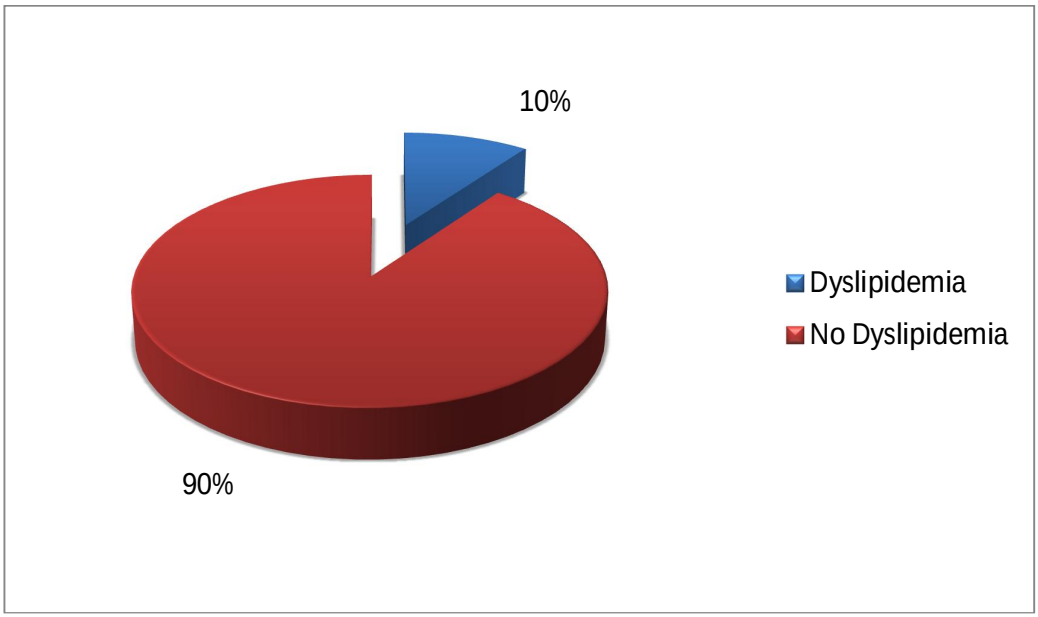
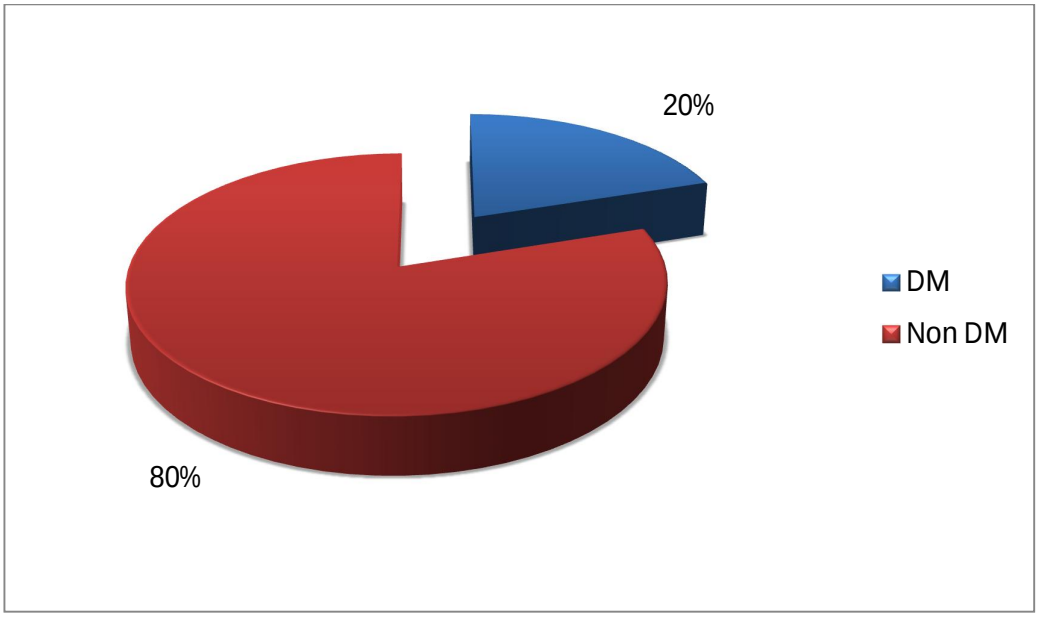
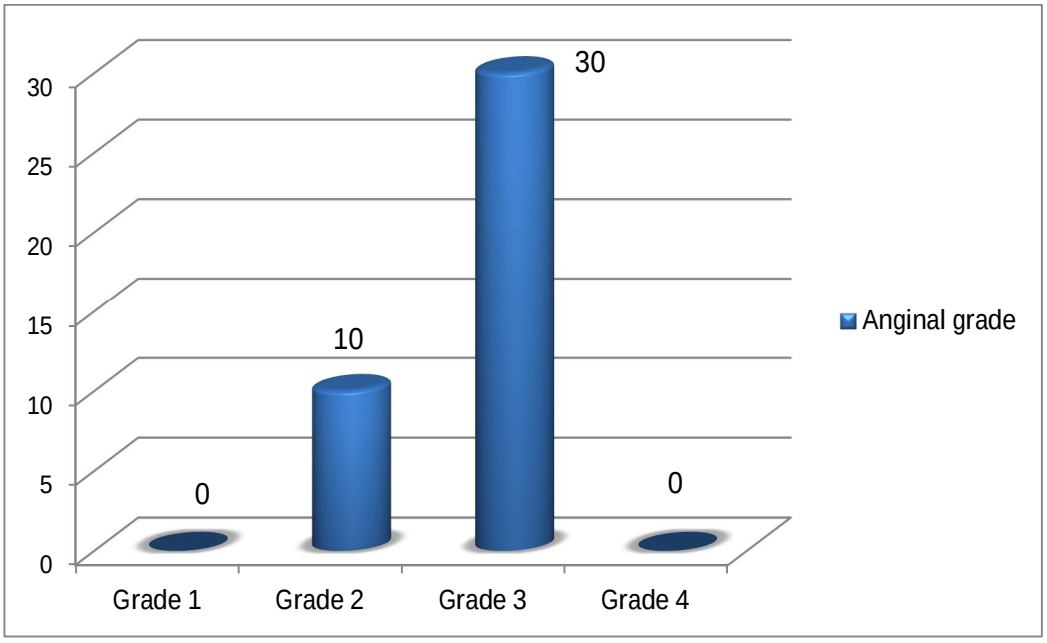


Figure 6: Showing Prevalence of Diabetes Mellitus



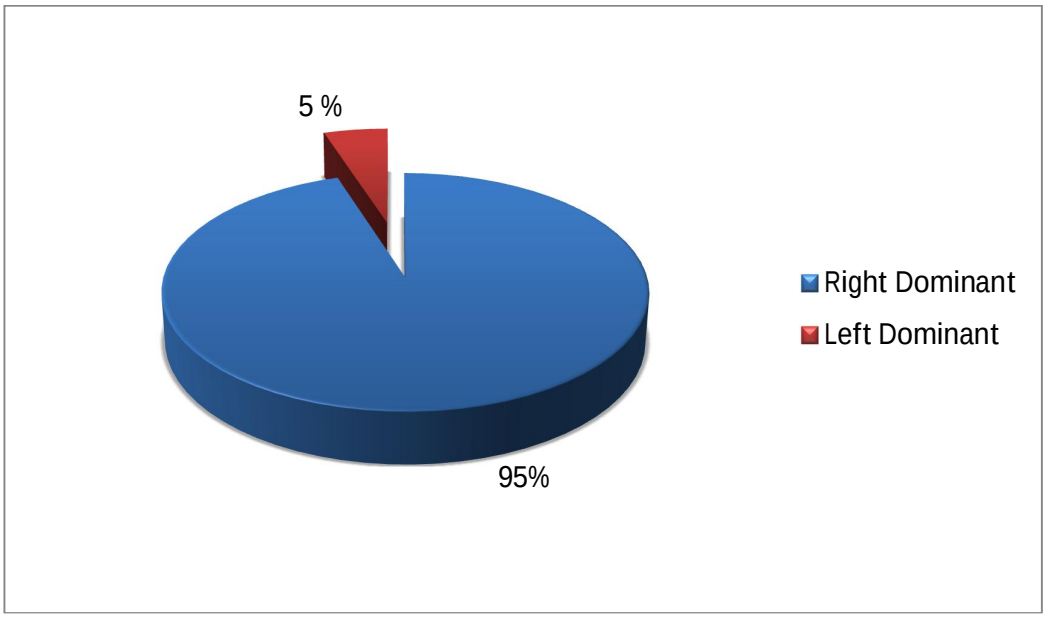
In our study population, 25 % of the patients was having NYHA grade 2 angina and they had recent deterioration of their anginal symptoms. 30 patients constituting 75 % of the study population was having NYHA class 3 angina. No patient was having Class 4 or rest angina and also Class 1 anginal symptoms were not also present. The anginal grades in study population is depicted in Figure no. 7.

Figure 7: Showing Anginal grade



In coronary angiogram, 38 patients were having right dominant circulation constituting about 95 % of the study population. Left dominance was present in 5 % of the patients and no patient was having co-dominance. The dominance pattern is depicted in Figure No. 8.

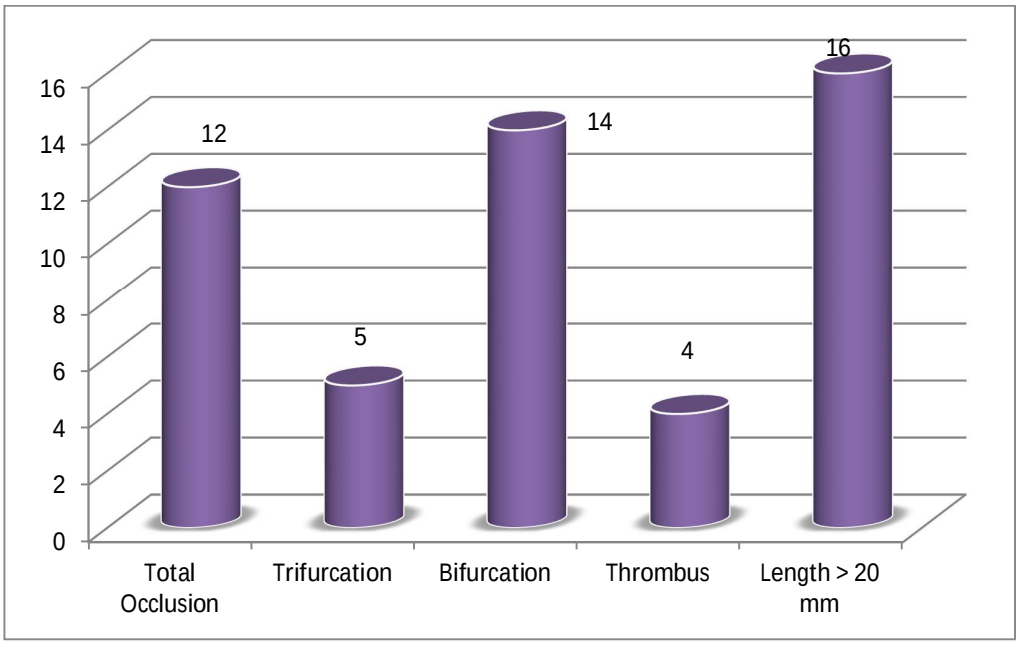
Figure 8: Showing Dominance of Coronary Circulation



Regarding lesion characteristics, total occlusion of 1 or more coronary arteries was seen in 12 patients constituting about 30 % . Trifurcation lesions were seen in 5 patients (12.5 %) and bifurcation lesions seen in 14 patients (35 %). Thrombus containing lesions were seen in 4 persons constituting about 10 % of the study population. Long lesions as defined by lesion length more than 20 mm was visualised in 16 patients constituting about 40 % of the study population.

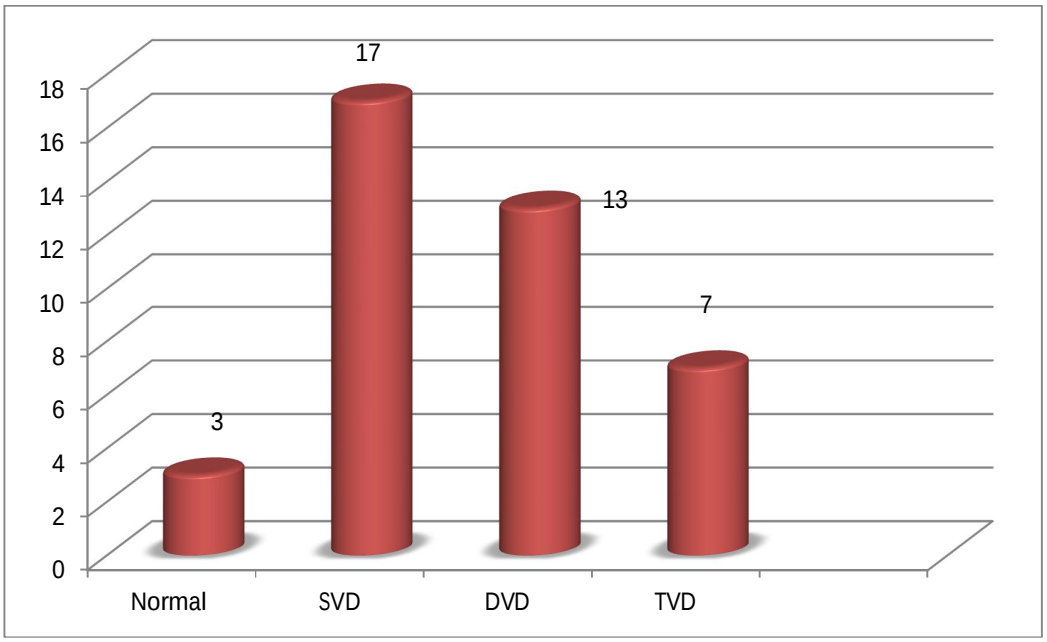
Calcified lesions, tortuosity and aorto-ostial lesions were not seen in our study. The lesion characteristics are depicted pictorially in Figure No. 9.

Figure 9: Lesion characteristics



In 40 patients who underwent coronary angiogram, 3 patients (7.5 %) were having angiographically normal epicardial arteries. Single vessel was seen 17 patients constituting about 42.5 % of the study population and form a major group. The remaining patients were having double vessel disease in 13 patients. Triple vessel disease was found in 7 patients constituting about 17.5 % of the study population. The details of number of vessels involved in shown in Figure No. 10.

Figure 10: Number of Vessels involved

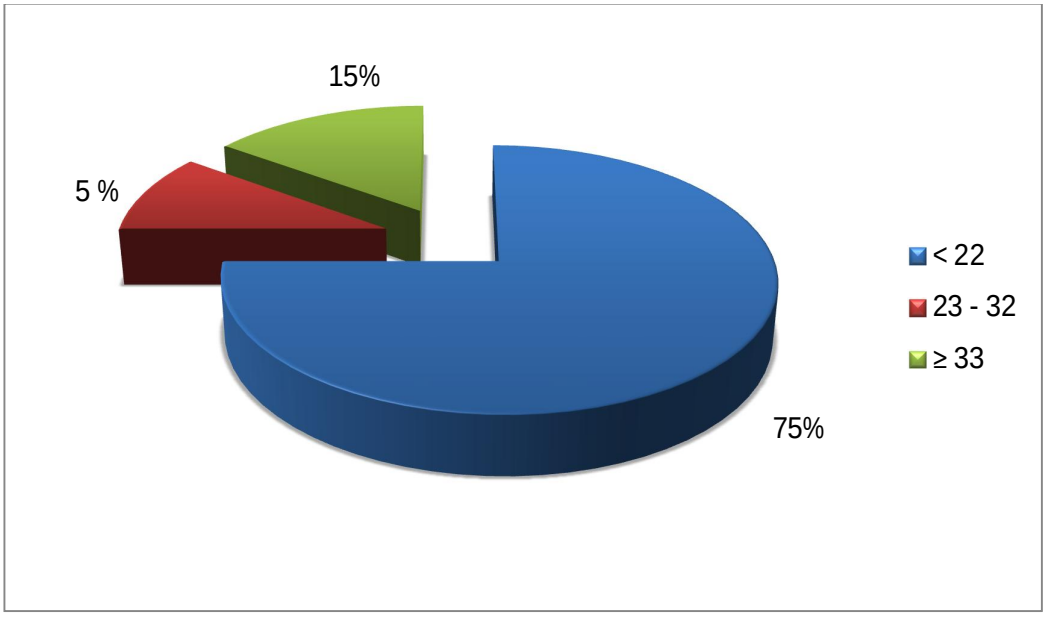


Patients with syntax score < 22 formed the major chunk in the study population. Patients having low syntax score form about 75 % of the population. High syntax score patients are those who are having syntax score more than 33. High syntax score was present in 6 patients in our study population constituting about 15 % of the study population. Intermediate syntax score which is the important group with therapeutic dilemma is seen in 4 persons forming 10 % of the study population. The details of patient population with syntax score groups is depicted in Table No.4 and in Figure No.11.

Table 4: distribution of patients according to syntax score

S. No.	Syntax Score	Number of Patients	Percentage
1	< 22	30	75 %
2	23 – 32	4	10 %
3	≥ 33	6	15 %

Figure 11: Distribution of patients according to syntax score



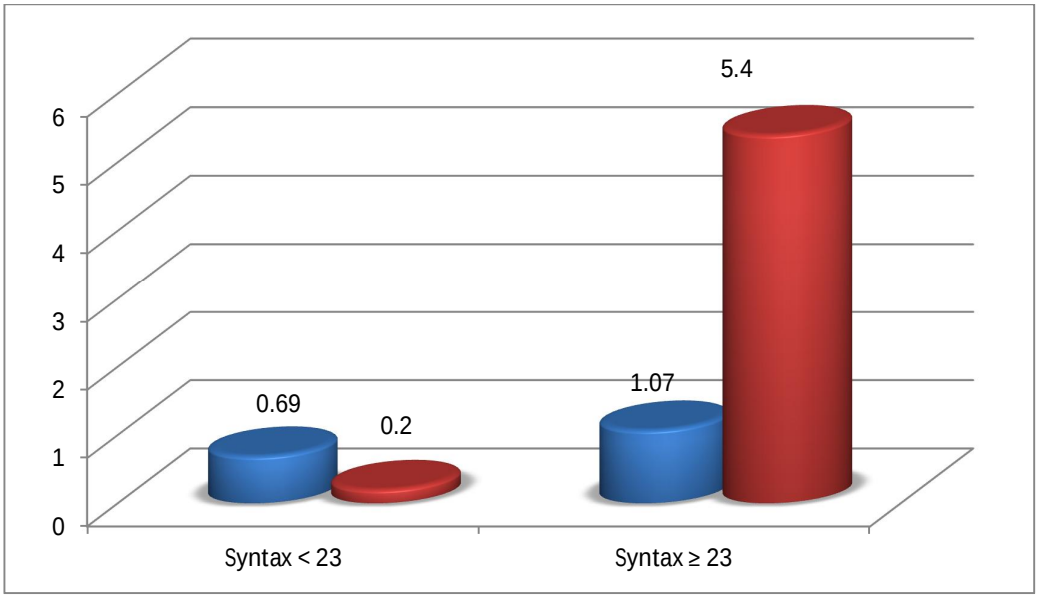
Regarding carotid intima media thickness, the mean intima media thickness in patients with low syntax score is 0.69 mm and in patients of intermediate and high syntax score is 1.07 mm. The difference between both means between these groups are statistically significant.

(p < 0.001). The Plaque score has mean of 0.20 in low syntax score group and 5.4 in intermediate and high syntax score group. The difference between these groups is statistically significant. (p < 0.0001). The details are depicted in Table No. 5 and inn Figure No. 12

Table 5: CIMT and Plaque score variations with Syntax score

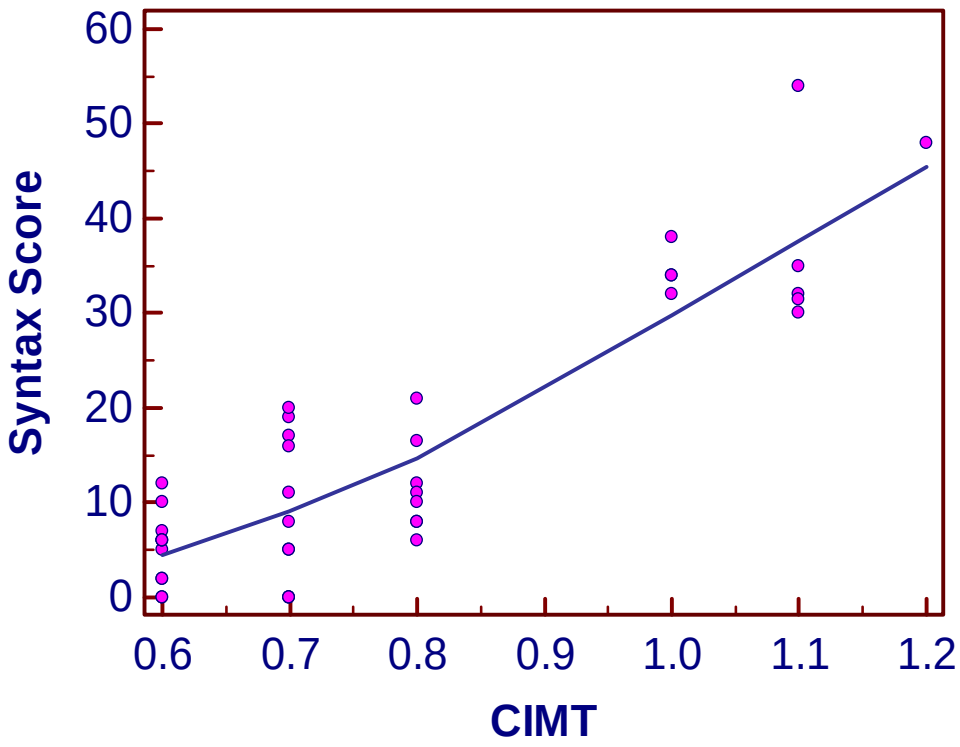
S. No	Syntax Score	CIMT	Plaque Score
		Mean ± SD	Mean ± SD
1	Low	0.69 ± 0.08	0.20 ± 0.55
2	Intermediate & High	1.07 ±0.07	5.40 ± 0.70
	p Value	< 0.0001	< 0.0001

Figure 12: CIMT and Plaque score variations with Syntax score



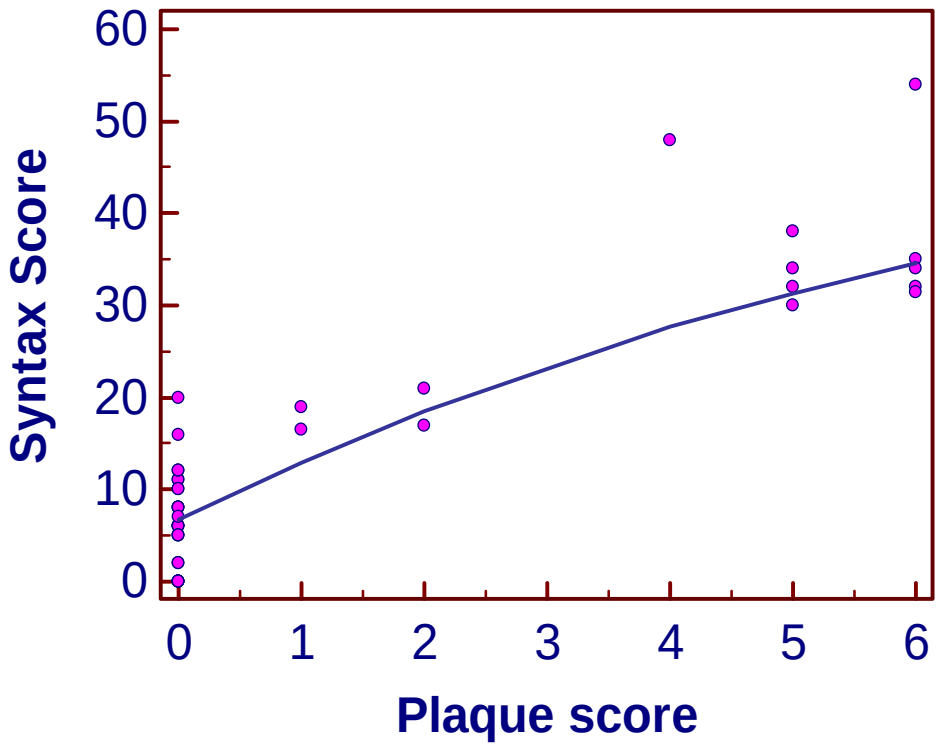
The main aim of the study is to analyse the correlation between syntax score and CIMT also with plaque score. There is positive correlation between syntax score and carotid intima-media thickness which is statisfically significant. (Spearman Coefficient 0.760 with p value < 0.0001). The scatter diagram with correlation is depicted in Figure 13.

Figure 13:Correlation between CIMT and syntax score



There is also positive correlation between syntax score and plaque score. The correlation is statistically significant. (Correllation coefficient = 0.825 with p value of < 0.0001). The correlation trend is depicted in scatter plot in Figure No. 14.

Figure 14: Correlation between Plaque score and syntax score



DISCUSSION

In our study population out of 40 patients, 32 patients were males and only 8 were females. This shows that males are more prone for coronary artery disease in our society. This may be due to high risky behaviour of smoking among males in our study population.

Among 32 males, 28 patients were smokers. Smoking is a major avoidable risk factor for the prevention of coronary artery disease. The prevalence of smoking is dangerously high in Indian men. Recent surveys indicate a prevalence rate of about 30% for smoking among men in India. Smoking ranks third in the health loss for India.

In our study about 10 patients belong to age group 40 – 50 years and 14 patients belong to age group 51 – 60 years together constituting 60 % of the study population. This shows the increasing incidence of cardiovascular disease in this age group. Dramatic changes in life style in diet, activity levels and smoking is responsible for this change. The above example shows that the study population is in the age of degenerative and manmade disease phase.

In our group 20 patients had hypertension. Accelerated hypertension was present in one individual. According to world health organisation health statistics[4] 2012, the prevalence of hypertension in India was 23.1 % in males and 22.6 % in females. But in our study, the incidence of hypertension is 50 %. This may be probably due to the high risk population of chest pain we have selected. More over it included patients with high burden of atherosclerosis which indicates that the patients have involvement of the peripheral arteries which might lead to

increase in systemic vascular resistance which could lead on to hypertension.

The high blood pressure is a high risk factor for stroke and coronary artery disease. The mortality due to stroke increases by about 51 % and mortality due to coronary artery disease increases by 45 %. High prevalence of hypertension in low and middle income class are due to increased smoking, high alcohol consumption and stress.

The high prevalence of hypertension in affluent population is due to physical inactivity and dietary changes. In our study population, there is high incidence of smoking and excessive consumption of alcohol, which might be the reason for the high incidence of systemic hypertension in our study population. Even though alcohol is beneficial in low doses, it has a narrow therapeutic to toxic range.

There are 8 patients in our study with diabetes mellitus which constituted about 20 %. According to International diabetic Foundation, India is having more diabetic patients than any other country. India has 7.1 % adult population with diabetes mellitus. The high incidence is attributed to a combination of genetic susceptibility and adoption of high calorie, low activity life style by India’s growing middle class.

Patients with past history of coronary artery disease, Family history of coronary disease and dyslipidemia did not form a significant part of our study.

In our study population all patients had baseline electro cardio graphic changes except for one patient who had normal electrocardiogram but with positive stress test change at low work load.

In our study population 38 patients had right dominance in coronary artery system which constituted 95 %. In the general population, the incidence of right dominance was 85 %. Right dominance in coronary circulation carries a less significance weightage in the syntax scoring system and our population had 10 % excess of right dominant population. Small study sample may be the reason for this observation.

The incidence of total occlusion of coronary artery in chronic stable angina is about 20 % whereas in our study population it is 30 %. The presence of total occlusion increases the complexity of coronary artery disease and thereby increases the syntax score significantly. Total occlusion carries a weightage of X 5 points.

Trifurcation and bifurcation lesions are present in about 18 patients who also increase the complexity of CAD and influence syntax score considerably.

In our study population those with syntax score less than 22 constitute the major chunk. In a study done by Nobutaka et al, it has been shown that low syntax scores were present in 80% of their population. (syntax score < 22).

In the intermediate syntax score group consisted of 7.5 % of patients (syntax score between 22 and 32), the high syntax score group consisted of 7.5 % of patients (syntax score > 33). In our study 75 % of patients had low syntax scores, 10 % had intermediate syntax score and 15 % had high syntax score.

Our study population with respect to syntax score, somewhat resembles the study population of the above author. Those with low

syntax score, the mean carotid intima media thickness was 0.69 mm and the mean plaque score was 0.2. In this aspect our study resembles the study done in various others parts of world and those with intermediate and high syntax score had mean carotid intima media thickness about 1.07 mm and mean plaque score of 5.4 which is also consistent with many other studies.

Thus carotid ultra sonogram parameters have a significant predictive value for the syntax score. More over the mean intima media thickness and plaque score have excellent negative predictive value for the presence of complex coronary artery disease.

Thus the usage of CIMT and plaque score which can be done easily, with best reproducibility will help us to negatively predict the presence of complex coronary artery disease estimated by the high value of syntax score.

LIMITATIONS OF THE STUDY

Small study population of the study is a strong limitation to the applicability of this test in the general population.

The relationship between CIMT and syntax score carries a strong correlation but causative conclusions cannot be made by the estimation of carotid intima media thickness alone. It reveals the underlying burden of atherosclerosis only.

CONCLUSIONS

There is a significant correlation between carotid intima media thickness and plaque score with that of intermediate and high syntax score.

Those with low CIMT and Plaque score helps us to negatively predict the presence of complex coronary artery disease.

Smoking in our study population is significantly high.

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1.Department of cardiology. Ahi Evre Cardiovascular and thoracic surgery Training and Research Hospital, Trabzon,Turkey.

2.Department of Radiology, school of medicine, Karadeniz Technical university, Trabzon, Turkey.

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ACRONYMS

RHD	-	Rheumatic Heart Disease
CHD	-	Coronary Heart Disease
CVD	-	Cardiovascular Disease
DM	-	Diabetes Mellitus
IVUS	-	Intra Vascular Ultra Sonogram
WHO	-	World Health Organization
CIMT	-	Carotid intima – media thickness
AHA	-	American Heart Association
ARTS	-	Arterial Revascularization Therapies Study
RCA	-	Right Coronary Artery
LCA	-	Left Coronary Artery
LAD	-	Left Anterior Descending Artery
LCX	-	Left Circumflex Artery
LM	-	Left Main Artery
ACC	-	American College of Cardiology
ICPS	-	Institut Cardiovascularie Paris Sud

RD	-	Right Dominance
LD	-	Left Dominance
MHz	-	Mega Hertz
US	-	Ultra Sonogram
CAD	-	Coronary Artery Disease
NYHA	-	New York Heart Association
BMI	-	Body mass Index
JVP	-	Jugular Venous Pulse
ECG	-	Electro Cardiogram

STUDY OF RELATIONSHIP BETWEEN CAROTID INTIMA-MEDIA THICKNESS AND SYNTAX SCORE IN PATIENTS WITH CORONARY ARTERY DISEASE

PROFORMA

NAME AGE / SEX

IP/OP NO. ADDRESS

DIABETES MELLITUS

HYPERTENSION Y/N

CAD ANGINA / MI

HF

PVD

SMOKER

ALCOHOLIC

MENSTRUAL STATUS

FAMILY H/O CAD

VITALS

HT WT BMI WAIST/HIP RATIO

CLINICAL FEATURES

ECHO

LIPID PROFILE

CAG SVD

DVD

TVD

TYPE OF LESION A B C

SYNTAX SCORE

LMCA DISEASE

MINIMAL CAD

NORMAL

COLLATERALS

MASTER CHART

S. No	Sex	Age	Smoking	Dyslipidemia	HTN	DM	Menopause	Elderly	Family H/o	Alcohol	Past H/o CAD	Symptoms	ECG	ECHO	Dominance	No. of lesions	Total Occlusion	Trifurcation	Bifurcation	Lenth>20 mm	Thrombus	Diffuse/small	No. of vessels diseased	Syntax	CIMT in mm	Plaque score
1	2	58	0	0	1	1	1	0	1	0	1	3	T ↓ant	N	1	3	2	0	0	0	0	0	2	31.5	1.1	6
2	1	37	1	0	0	0	0	0	0	1	0	3	RBBB	N	1	2	1	0	0	0	0	0	2	16.5	0.8	1
3	2	48	0	0	0	0	0	0	1	0	0	3	T ↓inf	N	1	1	0	0	1	0	0	0	1	6.0	0.6	0
4	2	65	0	0	1	1	1	1	0	0	1	3	qs inf	50%	1	5	2	0	1	1	1	1	3	34.0	1.0	6
5	1	37	1	0	1	0	0	0	0	1	0	3	T ↓ ant	N	1	1	0	0	0	0	0	0	1	0.0	0.7	0
6	1	52	1	0	1	1	0	0	0	1	0	2	qs inf	N	2	2	0	0	0	1	0	0	2	10.0	0.8	0
7	1	51	1	0	0	0	0	0	0	1	1	3	T ↓ ant	54%	1	2	0	0	0	1	0	0	2	6.0	0.8	0
8	1	83	1	0	0	0	0	1	0	1	0	3	T ↓ ant	N	1	1	0	0	1	0	0	0	1	5.0	0.7	0
9	1	50	1	0	0	0	0	0	0	1	0	2	LAFB LVH	N	1	1	0	1	0	0	0	0	1	11.0	0.8	0
10	1	62	1	1	1	0	0	1	0	1	0	3	T ↓lat	N	1	0	0	0	0	0	0	0	0	0.0	0.6	0
11	1	52	1	0	1	0	0	0	0	1	0	3	qs inf	52%	1	4	1	0	0	1	0	1	2	19.0	0.7	1
12	1	63	0	0	1	1	0	1	0	0	0	3	T ↓lat	N	1	5	3	1	0	1	0	1	3	54.0	1.1	6
13	1	60	0	0	0	0	0	1	0	0	0	2	T ↓ ant	N	1	1	0	1	0	1	0	1	1	12.0	0.6	0
14	1	55	1	0	1	0	0	0	0	1	0	3	T ↓ ant	50%	1	1	1	0	1	0	0	0	1	6.0	0.6	0
15	1	30	1	0	0	0	0	0	0	1	0	3	T ↓ ant	N	1	1	0	0	1	0	1	0	0	6.0	0.6	0
16	1	46	0	0	1	0	0	0	0	1	0	3	qs inf	53%	1	5	0	0	1	1	0	1	3	32.0	1.0	6
17	1	26	1	0	0	0	0	0	0	1	0	3	T ↓ ant	N	1	1	0	0	0	0	0	0	1	5.0	0.7	0
18	2	43	0	0	0	0	0	0	0	0	0	2	T ↓inf	N	1	0	0	0	0	0	0	0	0	0.0	0.7	0
19	1	58	1	1	1	0	0	0	0	1	0	3	T ↓ ant	N	1	2	0	0	0	1	0	1	2	30.0	1.1	5
20	1	45	1	0	0	0	0	0	0	1	0	2	T ↓ ant	N	1	1	0	0	0	0	0	0	1	2.0	0.6	0
21	1	55	1	0	1	0	0	0	0	1	0	3	qs inf	53%	1	4	1	0	0	1	0	1	2	21.0	0.8	2
22	1	61	0	0	0	0	0	1	0	0	0	2	T ↓ lat	N	1	2	0	1	1	1	0	1	2	17.0	0.7	2
23	1	30	1	0	0	0	0	0	0	1	0	3	T ↓ ant	N	1	1	1	1	0	0	1	0	1	10.0	0.6	0
24	1	28	1	0	0	0	0	0	0	1	0	3	T ↓ ant	N	1	1	0	0	1	0	0	0	1	8.0	0.7	0
25	1	52	1	1	1	0	0	0	0	1	0	3	T ↓ ant	N	1	3	0	0	0	1	0	1	2	32.0	1.1	5
26	1	40	1	0	0	0	0	0	0	1	0	3	T ↓ ant	N	1	2	1	0	1	0	0	0	2	20.0	0.7	0
27	2	67	0	0	1	1	1	1	0	0	1	3	qs inf	52%	1	6	2	0	1	1	1	0	3	38.0	1.0	5
28	1	55	1	0	1	1	0	0	0	1	0	2	T ↓ ant	N	2	3	0	0	0	1	0	0	2	16.0	0.7	0
29	1	81	1	0	0	0	0	1	0	1	0	3	LAFB LVH	N	1	1	0	0	1	0	0	0	1	11.0	0.7	0
30	1	64	1	1	1	0	0	1	0	1	0	3	qs inf	N	1	1	0	0	0	0	0	0	1	5.0	0.6	0
31	1	61	0	0	1	1	0	1	0	0	0	3	T ↓ ant	N	1	5	3	1	0	1	0	1	1	48.0	1.2	4
32	1	58	1	0	1	0	0	0	0	1	0	3	LAFB LVH	51%	1	1	1	0	1	0	0	0	3	7.0	0.6	0
33	1	48	0	0	1	0	0	0	0	1	0	3	qs inf	54%	1	5	0	0	1	1	0	1	0	35.0	1.1	6
34	2	45	0	0	0	0	0	0	0	0	0	2	T ↓ inf lat	N	1	0	0	0	0	0	0	0	3	0.0	0.7	0
35	1	48	1	0	0	0	0	0	0	1	0	2	T ↓lat	N	1	1	0	0	0	0	0	0	1	2.0	0.6	0
36	2	56	0	0	1	1	1	0	1	0	1	3	T ↓ ant	N	1	3	2	0	0	0	0	0	2	34.0	1.0	5
37	2	49	0	0	0	0	0	0	1	0	0	3	T ↓ ant	N	1	1	0	0	1	0	0	0	1	8.0	0.8	0
38	1	37	1	0	1	0	0	0	0	0	0	3	T ↓ ant	N	1	0	0	0	0	0	0	0	1	0.0	0.6	0
39	1	54	1	0	0	0	0	0	0	1	1	3	qs inf	52%	1	2	0	0	0	1	0	0	2	8.0	0.8	0
40	1	51	1	0	0	0	0	0	0	1	0	2	T ↓ ant	N	1	1	0	1	0	0	0	0	1	12.0	0.8	0

Sex : 1 Male , 2 Female

Smoking : 1 Present, 0 Absent

Dyslipidemia : 1 Present, 0 Absent

HTN : 1 Present, 0 Absent

DM : 1 Present, 0 Absent

Elderly : 1 Present, 0 Absent

Alcohol : 1 Present, 0 Absent

DEPARTMENT OF CARDIOLOGY
MADRAS MEDICAL COLLEGE &
RAJ IV GANDHI GOVT. GENERAL HOSPITAL, CHENNAI-3

From
Dr. S.Retnaraj
Postgraduate in Cardiology,
Department of Cardiology,
Madras Medical College &
Rajiv Gandhi Govt. General Hospital,
Chennai- 600003.

To
The Chairman,
Institutional Ethics Committee,
Madras Medical College &
Rajiv Gandhi Govt. General Hospital,
Chennai -600 003.

Through Proper Channel.

Respected Sir,

Sub: Dissertation proposal titled "STUDY OF RELATIONSHIP BETWEEN CAROTID INTIMA- MEDIA THICKNESS AND SYNTAX SCORE IN PATIENTS WITH CORONARY ARTEREY DISEASE"- submitted for approval.

I propose to work on **STUDY OF RELATIONSHIP BETWEEN CAROTID INTIMA-MEDIA THICKNESS AND SYNTAX SCORE IN PATIENTS WITH CORONARY ARTERY DISEASE"-** submitted for approval under the guidance of Prof. Dr.M.S.Ravi M.D; D.M, Professor of Cardiology. I request the approval from the Institutional Ethics Committee (1EC). I am enclosing the details of the work.

I submit the following undertaking,

1. 1 will obtain detailed informed consent from all the patients in the study and maintain confidentiality.

2. I will carry out the work without detriment to regular activities and without extra expenditure to the institution and government.

3. I will inform the institutional Ethics Committee in case of any change in the procedure, site, investigation or guide.

4. I will not deviate from the area of work for which I had applied for ethical clearance.

5. I will inform the institutional Ethics Committee immediately in case of any serious adverse reactions.

6. I will abide by the rules and regulations of the institution.

7. I will complete the project within the specific period and will apply for permission again if an extension is required.

8. I will submit the summary of the project to the Institutional Ethics Committee on completion of the project.

9. I will not claim funds from the institution while doing the project or on its completion.

10. I understand that the members of the IEC have the right to monitor the proposed work at any time during the study period.

11. I am enclosing ten copies of the project proposal.

12. I have paid a sum of Rupees two hundred only under Head of Account "Student Development Fund".

Thanking you

Yours faithfully,

Guide and Supervisor:
Prof. Dr. M.S.Ravi M.D; DM,
Professor of Cardiology, Department of Cardiology,
Madras Medical Colleges & Rajiv Gandhi Govt. General Hospital,
Chennai – 600 003.

RECOMMENDATION OF THE HOD

The dissertation titled **"STUDY OF RELATIONSHIP BETWEEN CAROTID INTIMA-MEDIA THICKNESS AND SYNTAX SCORE IN PATIENTS WITH CORONARY ARTERY DISEASE"** will be done according to the regulations of the ethics committee and 1 recommend it for acceptance.

Prof. Dr. M.S.RAVI

Head of the Department
Department of Cardiology,
Madras Medical College & Rajiv Gandhi
Govt. General Hospital,
Chennai- 600003.

REMARKS OF THE GUIDE

The work will be done by Dr.S.Retnaraj on **"STUDY OF RELATIONSHIP BETWEEN CAROTID INTIMA-MEDIA THICKNESS AND SYNTAX SCORE IN PATIENTS WITH CORONARY ARTERY DISEASE**" under my supervision and I ensure that the candidate will abide by the rules of the ethics committee.

SIGNATURE OP THE GUIDE

Prof, Dr. M.S. Ravi , M.D; D.M,
Professor of Cardiology,
Department of Cardiology,
Madras Medical College,
Rajiv Gandhi Govt. General Hospital,
Chennai- 600003.

SIGNATURE OF CO- GUIDES

Prof. D.Muthukumar, M.D; DM
Professor of Cardiology
Department of Cardiology
Madras Medical College & Rajiv Gandhi Govt. General Hospital,
Chennai – 600 003.

Dr.S.Venkatesan, M.D; D.M
Senior Assistant Professor,
Department of Cardiology Madras Medical College & R.G.G.G.H
Chennai – 600 003.

DETAILS OF THE PROJECT PROPOSAL

Title	**STUDY OF RELATIONSHIP BETWEEN CAROTID INTIMA-MEDIA THICKNESS AND SYNTAX SCORE IN PATIENTS WITH CORONARY ARTERY DISEASE**
Aims and Objective	To analyse the relationship between carotid--US findings and the severity of the syntax score
Design of the Study **Duration of study**	Prospective observational study
Ethical Clearance	Applied
Consent	An informed consent will be obtained from all the patients
Material / Selection of Subjects	Patients undergoing first coronary angiography for stable CAD between January 2014 to March 2014 at the department of Cardiology, RGGGH, Chennai underwent sequential carotid Ultrasonogram.
Exclusion Criteria	Not willing for angiography; allergic to contrast underlying chronic kidney disease, heart failure acute myocardial infarction.
Methods/ Analysis	Routine investigations and details of angiography will be noted .syntax score was calculated and correlated with the mean intima-media thickness and plaque score.
Conflicts of interest	Nil
Financial support **Participant:** **Primary investigator**	Nil Dr. S. Retnaraj, Postgraduate in Cardiology, Department of Cardiology, Madras Medical College & Rajiv Gandhi Govt. General Hospital, Chennai – 600 003.

Supervisor & Guide	Prof. Dr. M.S.Ravi M.D; D.M Professor of Cardiology, Department of Cardiology, Madras Medical College & Rajiv Gandhi Govt. General Hospital, Chennai-600 003.
Co Guides	Prof. D.Muthukumar M.D; DM Professor of Cardiology, Department of Cardiology, Madras Medical College & Rajiv Gandhi Govt. General Hospital, Chennai – 600 003.
	Dr.S.Venkatesan M.D; D.M Senior Assistant Professor, Department of Cardiology, Madras Medical College & Rajiv Gandhi Govt. General Hospital, Chennai – 600 003.

PATIENT CONSENT FORM

Study Details: **STUDY OF RELATIONSHIP BETWEEN CAROTID INTIMA-MEDIA THICKNESS AND SYNTAX SCORE IN PATIENTS WITH CORONARY XRTERY DISEASE**

Study Centre : Department of Cardiology
Madras Medical College and
Rajiv Gandhi Government General Hospitals
Chennai - 600 003.

Patient may check (✓) these boxes:

I confirm that I have understood the purpose of procedure for the above study. I have the opportunity to ask question and all my questions and doubts have been answered to my complete satisfaction. ☐

I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving reason, without my legal rights being affected. ☐

I understand that the investigator of the clinical study, others working on his behalf, the ethical committee and the regulatory authorities will not need my permission to look at my health records, both in respect of current study and any further research that may he conducted in relation to it, even if I withdraw from the study. However, I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from this study. ☐

I agree to take part in the above study and to comply with the instructions given during the study and faithfully cooperate with the study team and to immediately inform the study staff if I suffer from any deterioration in my health or well being or any unexpected or unusual symptoms. ☐

I hereby give permission to undergo complete clinical examination. ☐

I hereby consent to participate in this study. ☐

Signature / Thumb impression: Place: Date:

Patient Name and Address:

Signature of Investigator: Place: Date of Study

Investigator's Name:

INFORMATION SHEET

- We are conducting a study on the "study of relationship between carotid intima-media thickness and syntax score of coronary artery disease" at the Department of Cardiology, Rajiv Gandhi Govt. General Hospital, Chennai. The purpose of this study is to analyse the Angiographic profile of coronary artery disease among stable CAD patients undergoing angiography during the period January 2014 to march 2014.

- The privacy of the patients in the research will be maintained throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will he shared.

- Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time. Your decision will not result in any loss of benefits to which you are otherwise entitled.

- The results of the study may be intimated to you at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment.

Signature of the Investigator **Signature of the Participant**

Date :

ஆராய்ச்சி தகவல் தாள்

சென்னை அரசு பொது மருத்துவமனையில் கரோனரி இதய நோயாளிகளுக்கு கரோட்டிட் இன்டிம தடிமன் மற்றும் சின்டாக்ஸ் எண் இடையிலான உறவை பற்றி ஆராய உள்ளோம்.

நீங்கள் இந்த ஆராய்ச்சியில் பங்கேற்க நாங்கள் விரும்புகிறோம். இந்த ஆராய்ச்சியில் பங்கேற்பதால் தங்களது நோயின் ஆய்வறிக்கையோ அல்லது சிகிச்சையோ பாதிக்கப்படாது என்பதையும் தெரிவித்துக் கொள்கிறோம்.

இந்த ஆராய்ச்சியின் முடிவுகளை அல்லது கருத்துகளை வெளியிடும் போதோ அல்லது ஆராய்ச்சியின் போதோ தங்களது பெயரையோ அல்லது அடையாளங்களையோ வெளியிடமாட்டோம் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

இந்த ஆராய்ச்சியில் பங்கேற்பது தங்களுடைய விருப்பத்தின் பேரில் தான் இருக்கிறது. மேலும் நீங்கள் எந்நேரமும் இந்த ஆராய்ச்சியில் இருந்து பின்வாங்கலாம் என்பதையும் தெரிவித்துக்கொள்கிறோம்.

இந்த சிறப்புப் பரிசோதனைகளின் முடிவுகளை ஆராய்ச்சியின் போதோ அல்லது ஆராய்ச்சியின் முடிவின் போதோ தங்களுக்கு அறிவிப்போம் என்பதையும் தெரிவித்துக்கோள்கிறோம்.

ஆராய்ச்சியாளர் கையொப்பம் பங்கேற்பாளர் கையொப்பம்

தேதி:

சுய ஒப்புதல் படிவம்

ஆய்வுசெய்யப்படும்தலைப்பு

கரோனரி இதய நோயாளிகளுக்க கரோட்டிட் இன்டிம தடிமன் மற்றும் சின்டாக்ஸ் எண் இடையிலான உறவை பற்றிய ஆராய்ச்சி.

ஆராய்ச்சி நிலையம்: இருதய மருத்துவத் துறை,
இராஜீவ் காந்தி அரசு பொது மருத்துவமன
மற்றும் சென்னை மருத்துவக்கல்லூரி, சென்னை – 600 003.

பங்கு பெறுபவரின் பெயர்: உறவு முறை:

பங்கு பெறுபவரின் எண்:

பங்கு பெறுபவர் இதைன (√) குறிக்கவும்

மேலகுறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது. என்னுடைய சந்தேகங்களைக் கேட்கவும், அதற்கான தகுந்த விளக்கங்களைப் பெறவும் வாய்ப்பளிக்கப்பட்டது. ☐

நான் இவ்வாய்வில் தன்னிச்சையாகத்தான் பங்கேற்கிறேன். எந்தக் காரணத்தினாலோ எந்தக் கட்டத்திலும் எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நான் இவ்வாய்வில் இருந்து விலகிக் கொள்ளலாம் என்றும் அறிந்து கொண்டேன். ☐

இந்த ஆய்வு சம்மந்தமாகவும், மேலும் இது சார்ந்தஆய்வு மேற்கொள்ளும்போதும், இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளைப் பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்துகொள்கிறேன். நான் ஆய்வில் இருந்து விலகிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன். ☐

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும், பரிசோதனை முடிவுகளையும் மற்றும் சிகிச்சை தொடர்பான தகவல்களையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக் கொள்ளவும், அதைப் பிரசுரிக்கவும் என் முழு மனதுடன் சம்மதிக்கிறேன். ☐

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக்கொள்கிறேன். எனக்குக் கொடுக்கப்பட்ட அறிவுரைகளின் படி நடந்துகொள்வதுடன், இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்றும் உறுதியளிக்கிறேன். என் உடல் நலம் பாதிக்கப்பட்டாலோ அல்லது எதிர்பாராத வழக்கத்திற்கு மாறாக நோய்க்குறி தென்பட்டாலோ உடேன அைத மருத்துவ அணியிடம் தெரிவிப்பேன் என உறுதி அளிக்கிறேன். ☐

இந்த ஆய்வில் எனக்கு மருத்துவப் பரிசோதனை, **இன்டிம தடிமன் பரிசோதனை மற்றும் இதய உட்புகு பரிசோதனை செய்து கொள்ள** நான் முழு மனதுடன் சம்மதிக்கிறேன். ☐

பங்கேற்பவரின் கையொப்பம் ..... இடம் ..... தேதி.....

கட்டைவிரல் ரேகை

பங்கேற்பவரின் பெயர் மற்றும் விலாசம் .....

ஆய்வாளரின் கையொப்பம் ..... இடம் ..... தேதி.....

ஆய்வாளரின் பெயர் .....

INSTITUTIONAL ETHICS COMMITTEE

MADRAS MEDICAL COLLEGE, CHENNAI – 600 003.

EC Reg. No. ECR /270/Inst/TN/2013

Telephone No. 044 25305301

Fax 044 25363970

CERTIFICATE OF APPROVAL

To

Dr.S.Retnaraj,

Post graduate in DM Cardiology,

Department of Cardiology,

Madras Medical College, Chennai 600 003.

Dear Dr.S.Retnaraj

, The Institutional Ethics Committee of Madras Medical College , reviewed and discussed your application for approval of the proposal**"STUDY OF RELATIONSHIP BETWEEN CAROTID INTIMA-MEDIA THICKNESS AND SYNTAX SCORE IN PATIENTS WITH CORONARY ARTERY DISEASE."** . NO. 22022014

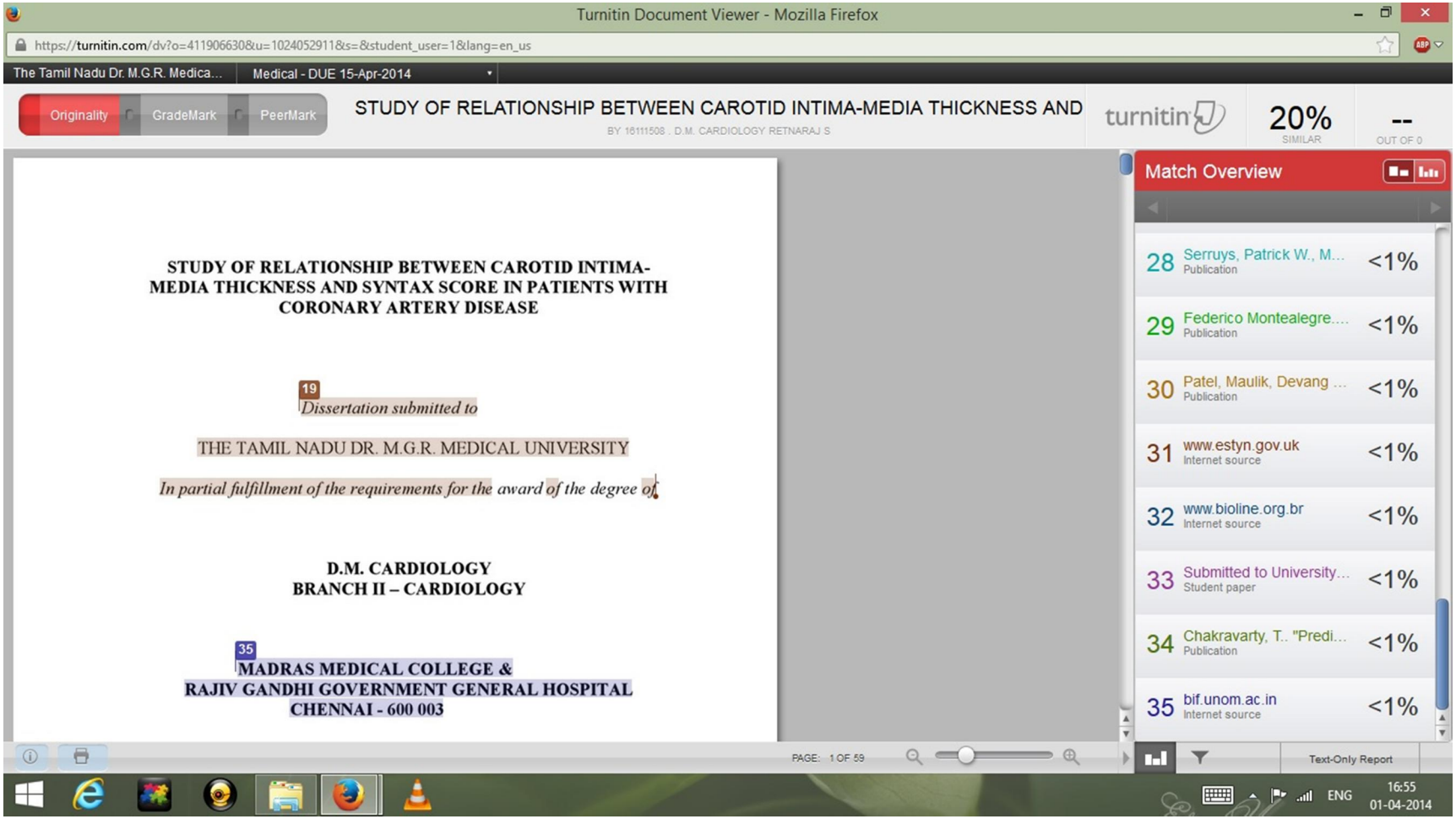
The following members of the Ethical Committee were present in the meeting held on 04.02.2014 conducted at Madras Medical College, Chennai – 3.

1. Dr .G.Sivakumar , MS FICS FAIS Chairperson
2. Prof.B.Kalaiselvi , MD
   Vice Principal, MMC, Ch3 Member Secretary
3. Prof.Ramadevi ,
   Director i/c, Institute of Biochemistry, Chennai Member
4. Thiru .S.Govidasamy , BA., BL., Lawyer
5. Tmt .ArmoldSaulina , MA MSW Social Scientist

We approve the proposal to be conducted in its present form.
Sd / Chairman & other Members.
The Institutional Ethics Committee expects to be informed about the progress of the study , and SAE occurring in the course of the study , any changes in the protocol and patients information / informed consent and asks to be provided a copy of the final report.

Member Secretary , Ethics Committee

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
CHENNAI-600 003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In partial fulfillment of the requirements for the award of the degree of
D.M. CARDIOLOGY
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